Therapeutic Goods Act 1989

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Volume 1: sections 1-41A
Volume 2: sections 41B-69
Endnotes

Each volume has its own contents

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods Act 1989* that shows the text of the law as amended and in force on 5 September 2025 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au).

Application, saving and transitional provisions

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Presentational changes

The *Legislation Act 2003* provides for First Parliamentary Counsel to make presentational changes to a compilation. Presentational changes are applied to give a more consistent look and feel to legislation published on the Register, and enable the user to more easily navigate those documents.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. Any modifications affecting the law are accessible on the Register.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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An Act relating to therapeutic goods

Chapter 1—Preliminary

1 Short title

This Act may be cited as the *Therapeutic Goods Act 1989*.

2 Commencement

This Act commences on the day after the day on which a House of the Parliament approves regulations made under this Act in the same form as approved by the other House, provided that:

(a) not more than 90 days have elapsed; and

(b) the places of Senators have not become vacant under section 13 of the Constitution; and

(c) a dissolution or expiration of the House of Representatives has not occurred;

between the approval of one House and the approval of the other House.

3 Interpretation

(1) In this Act, unless the contrary intention appears:

accessory, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable or assist the device to be used as the manufacturer of the device intended.

actual or potential tampering has the meaning given by section 42U.

advertise, in relation to therapeutic goods or vaping goods, includes make any statement, pictorial representation or design that

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is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

(a) is on the label of the goods; or

(b) is on the package in which the goods are contained; or

(c) is on any material included with the package in which the goods are contained.

anthroposophic pharmacopoeia means:

(a) a publication specified under paragraph 3AB(3)(a), as that publication is in force from time to time; or

(b) a part of a publication specified under paragraph 3AB(3)(b), as that part is in force from time to time.

anthroposophic preparation has the meaning given by subsection 3AB(1).

anthroposophic standard has the meaning given by subsection 3AB(2).

application audit assessment fee means a fee payable under subsection 41LA(3).

assessment fee means:

(a) a conformity assessment fee; or

(b) an application audit assessment fee; payable under Part 4-10.

Australian conformity assessment body means an Australian corporation that is the subject of a conformity assessment body determination made under the regulations.

Australian conformity assessment body certificate means a certificate that is issued by an Australian conformity assessment body and that is of a kind mentioned in section 41FIA.

Australian corporation means a corporation that is registered under Part 2A.2 of the *Corporations Act 2001*.

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Australia-UK Mutual Recognition Agreement means the Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates And Markings between the Government of Australia and the Government of the United Kingdom of Great Britain and Northern Ireland, as in force from time to time.

Note: The Agreement could in 2020 be viewed in the Australian Treaties Library on the AustLII website (http://www.austlii.edu.au).

authorised person means:

(a) in relation to any provision of this Act or the regulations, a person authorised by the Secretary to exercise powers under that provision; or

(b) in relation to a provision of Part 6-2 or 6-2A, a member of the Australian Federal Police, or a Customs officer exercising powers in a Customs place (within the meaning of section 183UA of the *Customs Act 1901*).

batch means a quantity of a product that is:

(a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and

(b) made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

bioburden, in relation to therapeutic goods, means the quantity and characteristics of microorganisms present in the goods or to which the goods may be exposed in a manufacturing environment.

biological has the meaning given by section 32A.

biological number of a biological means:

(a) the number assigned to the biological under subsection 32DB(2), 32DCB(2), 32DF(2) or 32DN(5); or

(b) if, in accordance with regulations made for the purposes of paragraph 9A(4)(ca), a different number is assigned to the biological—that different number.

British Pharmacopoeia means the edition of the publication of that name, including any additions or amendments, that was in effect

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for the purposes of this Act immediately before the commencement of Schedule 4 to the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009* and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the British Pharmacopoeia Commission or any replacement body.

certification-related activities, when used in relation to an Australian conformity assessment body, means activities that consist of, or relate to, the issue of certificates as mentioned in section 41FIA.

civil penalty provision has the meaning given by section 42YA.

Class 1 biological means a biological, other than an export only biological, included in a class of biologicals that is:

(a) a class prescribed by the regulations for the purposes of section 32AA; and

(b) a class referred to in those regulations as Class 1 biologicals.

commercial quantity of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

Commonwealth authority includes:

(a) a body corporate, or an unincorporated body, established for a public purpose by or under an Act; and

(b) a tribunal or authority established by or in accordance with an Act.

Commonwealth officer includes:

(a) a Minister; and

(b) a person holding:

(i) an office established by or under an Act; or

(ii) an appointment made under an Act; or

(iii) an appointment made by the Governor-General or a Minister but not under an Act; and

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(c) a person who is a member or officer of a Commonwealth authority; and

(d) a person who is in the service or employment of the Commonwealth, or of a Commonwealth authority, or is employed or engaged under an Act or regulations made under an Act.

composite pack has the meaning given by subsection 7B(2).

Comptroller-General of Customs means the person who is the Comptroller-General of Customs in accordance with subsection 11(3) or 14(2) of the *Australian Border Force Act 2015*.

conformity assessment body determination has the meaning given by section 41EWA.

conformity assessment certificate means a certificate issued under section 41EE.

conformity assessment document means:

(a) a conformity assessment certificate; or

(b) an Australian conformity assessment body certificate; or

(c) an overseas regulator conformity assessment document.

conformity assessment fee means a fee payable under subsection 41LA(1).

conformity assessment procedures has the meaning given by section 41DA.

conformity assessment standard means a conformity assessment standard specified in an order under section 41DC.

container, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.

corporation means a body corporate that is:

(a) a foreign corporation; or

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(b) a trading corporation formed within the limits of the Commonwealth or a financial corporation so formed.

corresponding State law means a State law declared by the regulations to correspond to this Act or the regulations, including such a law as amended from time to time.

counterfeit has the meaning given by section 42E.

current Poisons Standard has the meaning given by section 52A.

Customs officer means an officer of Customs within the meaning of the *Customs Act 1901*.

data processing device means any article or material (for example, a disc) from which information is capable of being reproduced with or without the aid of any other article or device.

default standard means any of the following:

(a) a standard referred to in paragraph (b) of the definition of ***standard*** in this subsection;

(b) a standard referred to in paragraph (c) of that definition;

(c) a standard referred to in paragraph (d) of that definition.

device number, in relation to a medical device, means any combination of numbers, symbols and letters assigned to the device under section 41FL.

directions for use, in relation to therapeutic goods, includes information on:

(a) appropriate doses of the goods; and

(b) the method of administration or use of the goods; and

(c) the frequency and duration of treatment for each indication of the goods; and

(d) the use of the goods by persons of particular ages or by persons having particular medical conditions.

EC/EFTA attestation of conformity means an attestation of conformity (within the meaning of the EC Mutual Recognition

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Agreement or the EFTA Mutual Recognition Agreement) issued by an EC/EFTA conformity assessment body that is approved by the Secretary in writing.

EC/EFTA conformity assessment body means a Conformity Assessment Body designated in one of the following Sectoral Annexes to the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement:

(a) Sectoral Annex (Medical Devices);

(b) Sectoral Annex (Medicinal Products GMP Inspection and Batch Certification).

EC Mutual Recognition Agreement means the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community, as in force from time to time.

EFTA Mutual Recognition Agreement means the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Free Trade Association, as in force from time to time.

essential principles has the meaning given by section 41CA.

ethics committee means a committee:

(a) constituted and operating as an ethics committee in accordance with guidelines issued by the CEO of the National Health and Medical Research Council as in force from time to time; and

(b) which has notified its existence to the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992*.

European Pharmacopoeia means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or

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amendments, or those new editions, from the effective date published by the Council of Europe or any replacement body.

evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

exempt device means a medical device that is of a kind that is exempted from Division 3 of Part 4-11 by the regulations.

exempt goods, in relation to a provision of Part 3-2, means therapeutic goods that are exempted from the operation of that Part (except section 31A and sections 31C to 31F) by the regulations.

exempt goods, in relation to a provision of Part 3-3, means therapeutic goods that are exempted from the operation of that Part by the regulations.

exempt person, in relation to therapeutic goods, means a person exempted from the operation of Part 3-3 in relation to those goods by the regulations.

export only biological means a biological that is:

(a) manufactured in Australia for export only; or

(b) imported into Australia for export only.

export only medicine means a medicine that:

(a) is manufactured in Australia for export only, or imported into Australia for export only; and

(b) is listable goods only because it is so manufactured or imported (and not for any other reason).

Federal Court means the Federal Court of Australia.

financial corporation means a financial corporation within the meaning of paragraph 51(xx) of the Constitution.

first Poisons Standard has the meaning given by section 52A.

foreign corporation means a foreign corporation within the meaning of paragraph 51(xx) of the Constitution.

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gazetted kits group means a group of kits identified in an order in force under subsection 16(3A).

gazetted therapeutic goods group has the meaning given by subsection 16(2).

Gene Technology Regulator has the same meaning as in the *Gene Technology Act 2000*.

genetically modified organism has the same meaning as in the *Gene Technology Act 2000*.

GM product has the same meaning as in the *Gene Technology Act 2000*.

grouped therapeutic goods means therapeutic goods included in:

(a) a gazetted therapeutic goods group; or

(c) a gazetted kits group.

healthcare facility means:

(a) a public hospital; or

(b) a private hospital; or

(c) any other facility prescribed by regulations made for the purposes of this paragraph.

health practitioner means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

(a) Aboriginal and Torres Strait Islander health practice;

(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);

(c) medical;

(d) medical radiation practice;

(e) nursing;

(f) midwifery;

(g) occupational therapy;

(h) optometry;

(i) pharmacy;

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(j) physiotherapy;
(k) podiatry;
(l) psychology.

homoeopathic pharmacopoeia means:
(a) a publication specified under paragraph 3AA(3)(a), as that publication is in force from time to time; or
(b) a part of a publication specified under paragraph 3AA(3)(b), as that part is in force from time to time.

homoeopathic preparation has the meaning given by subsection 3AA(1).

homoeopathic standard has the meaning given by subsection 3AA(2).

hospital has the meaning given by subsection 121-5(5) of the *Private Health Insurance Act 2007*.

included in the Register:
(a) in relation to a biological—means included in the Register under Part 3-2A; and
(b) in relation to a medical device to which Chapter 4 applies— means included in the Register under Chapter 4.

indications, in relation to therapeutic goods, means the specific therapeutic uses of the goods.

international instrument means:
(a) any treaty, convention, protocol, agreement or other instrument that is binding in international law; and
(b) a part of such a treaty, convention, protocol, agreement or other instrument.

issuing officer means:
(a) a magistrate; or
(b) a registrar or other officer of a court of a State or Territory who is authorised under a law of the State or Territory to issue search warrants.

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kind, in relation to a medical device, has the meaning given by section 41BE.

label, in relation to therapeutic goods, means a display of printed information:

(a) on or attached to the goods; or

(b) on or attached to a container or primary pack in which the goods are supplied; or

(c) supplied with such a container or pack.

licence means a licence under Part 3-3.

listable goods means therapeutic goods that are required under the regulations to be included in the part of the Register relating to listed goods.

listed goods means therapeutic goods that are included in the Part of the Register for goods known as listed goods.

listing number, in relation to listed goods, means any combination of numbers, symbols and letters assigned to the goods under section 27.

major interest holder of a body corporate means a person who:

(a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or

(b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

manufacture, in relation to therapeutic goods, or vaping goods, that are not medical devices, means:

(a) to produce the goods; or

(b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the

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goods or of any component or ingredient of the goods as part of that process.

manufacturer, of a medical device, has the meaning given by section 41BG.

manufacturing principles means the principles for the time being having effect under section 36.

manufacturing site means premises:

(a) that are for use in the manufacture of a particular kind of therapeutic goods; and

(b) at which the same persons have control of the management of the production of the goods and the procedures for quality control.

manufacturing site authorisation means an authorisation referred to in subsection 38(2B) or 40B(4).

medical device has the meaning given by section 41BD.

medical device classification means a classification specified in the regulations made for the purposes of section 41DB.

medical device standard, in relation to a kind of medical device, means a medical device standard, specified in an order under section 41CB, that is applicable to that kind of medical device.

medical practitioner means a person who is registered or licensed as a medical practitioner under a law of a State or an internal Territory that provides for the registration or licensing of medical practitioners.

medicine means therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.

member of EFTA means a country declared by the Minister under section 3A to be a member of the European Free Trade Association.

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member of the European Community means a country declared by the Minister under section 3A to be a member of the European Community.

mother substance means any of the following:

(a) an animal;

(b) a plant;

(c) an alga;

(d) a fungus;

(e) a micro-organism;

(f) a mineral;

(g) a mineral compound;

(h) a chemical;

(i) a product obtained from any of the things mentioned in paragraphs (a) to (h).

Mutual Recognition Convention means the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products done at Geneva on 8 October 1970.

national emergency declaration has the same meaning as in the *National Emergency Declaration Act 2020.*

non-EC/EFTA attestation of conformity, for a non-EC/EFTA MRA, means an attestation of conformity issued, after the non-EC/EFTA MRA has come into force, by a conformity assessment body that is designated in the non-EC/EFTA MRA and approved by the Secretary in writing for the non-EC/EFTA MRA.

non-EC/EFTA MRA means an international instrument that Australia is bound by, or is a party to, if:

(a) a purpose of the instrument is the recognition of attestations of conformity; and

(b) the instrument satisfies the requirements (if any) set out in regulations made for the purposes of this paragraph;

but does not include:

(c) the EC Mutual Recognition Agreement; or

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(d) the EFTA Mutual Recognition Agreement.

nurse practitioner means a person who is registered, or authorised (however described) to practise, as a nurse practitioner by or under a law of a State or an internal Territory that provides for the registration of nurse practitioners, or the authorisation of persons to practise as nurse practitioners.

oath includes affirmation.

overseas regulator has the meaning given by section 41BIB.

overseas regulator conformity assessment document means a certificate or other document that is issued by an overseas regulator after that regulator is satisfied that requirements, comparable to the conformity assessment procedures, have been applied to a medical device by the manufacturer of the device.

passed preliminary assessment:

(a) when used in relation to a section 23 application for registration—has the meaning given by subsection 23B(3); and

(b) when used in relation to a section 23 application for listing under section 26AE—has the meaning given by subsection 23B(3); and

(ba) when used in relation to a section 26BD application—has the meaning given by subsection 26BD(4); and

(c) when used in relation to a section 32DD application—has the meaning given by subsection 32DDA(3); and

(d) when used in relation to a section 41FC application—has the meaning given by subsection 41FDB(3).

period of a shortage of a medicine in Australia has the meaning given by section 30EIA.

personal information has the same meaning as in the *Privacy Act 1988*.

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pharmacist means a person who is registered as a pharmacist under a law of a State or an internal Territory that provides for the registration of pharmacists.

poison means an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard.

premises includes:

(a) a structure, building, aircraft, vehicle or vessel; and

(b) a place (whether enclosed or built upon or not); and

(c) a part of a thing referred to in paragraph (a) or (b).

presentation, in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

private hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a private hospital.

product information, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

protected information, in relation to therapeutic goods, has the meaning given by section 25A.

public hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a public hospital.

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quality, in relation to therapeutic goods, includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the goods.

refurbishment has the meaning given by the regulations.

Register means the Australian Register of Therapeutic Goods maintained under section 9A.

registered goods means:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

Note: Subsection (8) provides that a reference in this Act to therapeutic goods that are registered, or to the registration of therapeutic goods, includes a reference to a medicine that is provisionally registered under section 29.

registration number, in relation to registered goods, means any combination of numbers, symbols and letters assigned to the goods under section 27.

related body corporate has the same meaning as in the *Corporations Act 2001*.

reportable medical device means a medical device of a kind prescribed by regulations made for the purposes of this definition.

reportable medicine has the meaning given by section 30EH. ***restricted information*** has the meaning given by section 26AF. ***restricted medicine*** means:

(a) a medicine specified in an instrument under subsection (2A); or

(b) a medicine included in a class of medicine specified in an instrument under subsection (2B).

scheduling has the meaning given by section 52A.

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Secretary means the Secretary of the Department.

shortage of a medicine in Australia has the meaning given by section 30EI.

sponsor, in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

(d) exports, imports or manufactures the goods; or

(e) arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

standard, in relation to therapeutic goods, means any of the following:

(a) a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods;

(b) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1) in relation to the goods) in the British Pharmacopoeia—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2) in relation to the goods) in those monographs, as interpreted in accordance with the General Notices section of the British Pharmacopoeia;

(c) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1) in relation to the goods) in the European Pharmacopoeia—a standard that is constituted by the statements (other than

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statements exempt under subsection 3C(2) in relation to the goods) in those monographs, as interpreted in accordance with the General Notices section of the European Pharmacopoeia;

(d) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1) in relation to the goods) in the United States Pharmacopeia-National Formulary—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2) in relation to the goods) in those monographs, as interpreted in accordance with the General Notices section of the United States Pharmacopeia-National Formulary;

(e) a homoeopathic standard;

(f) an anthroposophic standard.

Note: See also section 13.

State includes the Australian Capital Territory and the Northern Territory.

State law means a law of a State, of the Australian Capital Territory or of the Northern Territory.

supply includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and

(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and

(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods or vaping goods in persons; and

(d) supply by way of administration to, or application in the treatment of, a person.

system or procedure pack has the meaning given by section 41BF.

tamper: therapeutic goods are tampered with if:

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(a) they are interfered with in a way that affects, or could affect, the quality, safety or efficacy of the goods; and

(b) the interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person.

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); or

(ba) determined to be therapeutic goods under subsection 7AAA(1);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7 and goods determined to be therapeutic goods under subsection 7AAA(1)) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or

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(f) goods (other than goods declared to be therapeutic goods under an order in force under section 7 and goods determined to be therapeutic goods under subsection 7AAA(1)) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented; or

(g) goods covered by a determination under subsection 7AA(1) (excluded goods); or

(h) goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination.

Therapeutic Goods Advertising Code means the code in force under section 42BAA.

therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

(b) influencing, inhibiting or modifying a physiological process in persons; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons.

trading corporation means a trading corporation within the meaning of paragraph 51(xx) of the Constitution.

unique device identifier of a medical device means any combination of numbers, symbols and letters given to the device to enable identification of the device (whether or not that combination also allows identification of information relating to the device).

unit of vaping goods has the meaning prescribed by the regulations.

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United States Pharmacopeia-National Formulary means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the United States Pharmacopeial Convention or any replacement body.

vaping accessory has the meaning given by section 41P. ***vaping device*** has the meaning given by section 41P. ***vaping goods*** has the meaning given by section 41P. ***vaping substance*** has the meaning given by section 41P. ***working day***, for a person, means any day except:

(a) Saturday or Sunday; or

(b) a day that is a public holiday in the State or Territory in which the person is located.

(2) For the purposes of this Act, therapeutic goods are taken to be for use in humans if they are not solely for use in animals.

(2A) The Minister may, by legislative instrument, specify medicines for the purposes of paragraph (a) of the definition of ***restricted medicine*** in subsection (1).

(2B) The Minister may, by legislative instrument, specify classes of medicine for the purposes of paragraph (b) of the definition of ***restricted medicine*** in subsection (1).

(4) The provisions of this Act are in addition to, and not in substitution for, the provisions of any other Act that relate to therapeutic goods.

(5) For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and,

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without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:

(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or

(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or

(c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or

(ca) if the therapeutic goods are medicine included in a class of medicine prescribed by the regulations for the purposes of this paragraph—if the medicine's label does not contain the advisory statements specified under subsection (5A) in relation to the medicine; or

(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or

(e) in prescribed cases.

(5A) The Minister may, by legislative instrument, specify advisory statements in relation to medicine for the purposes of paragraph (5)(ca).

(5B) For the purposes of subsection (5A), the Minister may specify different advisory statements for different medicines or different classes of medicine.

(6) A reference in this Act to an annual registration charge, an annual listing charge, an annual charge for inclusion in the Register, an annual licensing charge or an annual conformity assessment body determination charge is a reference to such a charge imposed under the *Therapeutic Goods (Charges) Act 1989*.

(7) A reference to an offence against this Act includes a reference to:

(a) an offence against the regulations; and

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(b) an offence against section 6 of the *Crimes Act 1914*, or section 11.1, 11.4 or 11.5 of the *Criminal Code*, in relation to an offence against this Act or the regulations; and

(c) an offence against section 136.1, 137.1 or 137.2 of the *Criminal Code* in relation to this Act or the regulations.

(7A) For the purposes of this Act, a corresponding State law ***imposes a duty*** on a Commonwealth officer or Commonwealth authority if:

(a) the corresponding State law confers a function or power on the officer or authority; and

(b) the circumstances in which the function or power is conferred give rise to an obligation on the officer or authority to perform the function or to exercise the power.

(8) To avoid doubt:

(a) a reference in this Act to therapeutic goods that are registered includes a reference to a medicine that is provisionally registered; and

(b) a reference in this Act to the registration of therapeutic goods includes a reference to the provisional registration of a medicine.

Note: Subsection 29(2) deals with the provisional registration of a medicine.

3AA Homoeopathic preparations and homoeopathic standards

Homoeopathic preparation

(1) For the purposes of this Act, a ***homoeopathic preparation*** is a preparation:

(a) manufactured from a mother substance; and

(b) manufactured in accordance with a manufacturing procedure described in a homoeopathic pharmacopoeia.

Homoeopathic standard

(2) For the purposes of this Act, if:

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(a) there are therapeutic goods that are a homoeopathic preparation; and

(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the homoeopathic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is a ***homoeopathic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that homoeopathic pharmacopoeia.

Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***homoeopathic pharmacopoeia*** in subsection 3(1):

(a) publications;

(b) parts of publications.

Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of subsection (2).

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3AB Anthroposophic preparations and anthroposophic standards

Anthroposophic preparation

(1) For the purposes of this Act, an ***anthroposophic preparation*** is a preparation:

(a) manufactured from a mother substance; and

(b) manufactured in accordance with a manufacturing procedure described in an anthroposophic pharmacopoeia.

Anthroposophic standard

(2) For the purposes of this Act, if:

(a) there are therapeutic goods that are an anthroposophic preparation; and

(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the anthroposophic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is an ***anthroposophic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that anthroposophic pharmacopoeia.

Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***anthroposophic pharmacopoeia*** in subsection 3(1):

(a) publications;

(b) parts of publications.

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Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of subsection (2).

3A Declaration—member of European Community

(1) The Minister may declare, in writing, that a country specified in the declaration is a member of:

(a) the European Community; or

(b) the European Free Trade Association.

(2) A declaration under subsection (1) must be published in the *Gazette* or on the Department's website.

3B Declaration—country covered by non-EC/EFTA MRA

(1) The Minister may declare, in writing, that a country specified in the declaration is covered by the non-EC/EFTA MRA specified in the declaration.

(2) A declaration under subsection (1) must be published in the *Gazette* or on the Department's website.

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3C Exempting monographs in pharmacopoeias

Exempting entire monographs

(1) The Minister may, by legislative instrument, determine that specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt in relation to specified therapeutic goods for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1). The determination applies to those monographs as in force from time to time.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

Exempting parts of monographs

(2) The Minister may, by legislative instrument, determine that specified statements in specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt in relation to specified therapeutic goods for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1). The determination applies to those statements and monographs as in force from time to time.

Incorporation of other instruments

(3) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under subsection (1) or (2) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

4 Objects of Act

(1) The objects of this Act are to do the following, so far as the Constitution permits:

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(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia;

(c) provide for a scheme allowing pharmacists to substitute certain medicine for other medicine if the Minister has declared there is a serious scarcity of the other medicine;

(d) provide for the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are:

(i) imported into Australia; or

(ii) manufactured in Australia; or

(iii) supplied in Australia, whether manufactured in Australia or elsewhere; or

(iv) exported from Australia.

(1A) The reference in paragraph (1)(a) to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.

(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.

5 Act to bind Crown

This Act binds the Crown in right of the Commonwealth, of each of the States, of the Australian Capital Territory and of the Northern Territory, but nothing in this Act renders the Crown

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liable to be prosecuted for an offence or to be subject to civil proceedings for a contravention of a civil penalty provision.

5A Application of the *Criminal Code*—extended geographical jurisdiction

Section 15.2 of the *Criminal Code* (extended geographical jurisdiction—category B) applies to offences against subsections 21A(1), (4) and (4A), sections 22A, 32DO and 41FE,
subsections 42DZD(1) and (2) and sections 42DZG, 42DZL, 42E
and 42T.

6 Operation of Act

(1) This Act (other than Part 4-8A or Part 6-1A) applies to:

(a) things done by corporations; and

(b) things done by natural persons or corporations in so far as those things are done:

(i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or

(ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or

(iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

Note: Part 4-8A is about mandatory reporting, by healthcare facilities, of adverse events involving medical devices.

(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.

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6AAA Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws

(1) A corresponding State law may confer functions or powers, or impose duties, on:

(a) a Commonwealth officer; or

(b) a Commonwealth authority.

(2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:

(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on Commonwealth officers or Commonwealth authorities; or

(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:

(a) is consistent with subsections (1) to (3); and

(b) is capable of operating concurrently with this Act.

6AAB When duty imposed

Application

(1) This section applies if a corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority.

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State legislative power sufficient to support duty

(2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:

(a) imposing the duty is within the legislative powers of the State concerned; and

(b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 6AAA to the imposition of the duty by the corresponding State law).

Commonwealth legislative power sufficient to support duty but State legislative powers are not

(3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.

(4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.

(5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:

(a) is within the legislative powers of the Commonwealth; and

(b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the Commonwealth officer or

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Commonwealth authority to the extent to which imposing such a duty would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative power of the Commonwealth.

(7) Subsections (1) to (6) do not limit section 6AAA.

6AAC Imposing duty under State law

(1) This section:

(a) applies only for the purposes of the application of the provisions of this Act or another law of the Commonwealth (with or without modification) as a law of a State by a provision of a corresponding State law; and

(b) does not apply for those purposes if the corresponding State law otherwise provides.

(2) If the corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority to do a particular thing, the duty is taken to be imposed by the corresponding State law to the extent to which imposing the duty:

(a) is within the legislative powers of the State; and

(b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(3) To avoid doubt, the corresponding State law does not impose the duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing the duty would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of the State.

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(4) If imposing on the Commonwealth officer or Commonwealth authority the duty to do that thing would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of both the State and the Commonwealth;

the corresponding State law is taken instead to confer on the officer or authority a power to do that thing at the discretion of the officer or authority.

6AAD Conferral of jurisdiction on federal courts

If:

(a) a provision of a corresponding State law purports to apply a provision of a law of the Commonwealth (the ***applied provision***) as a law of the State; and

(b) the applied provision purports to confer jurisdiction in relation to a matter on a federal court;

the jurisdiction in relation to that matter is taken to be conferred on the court by this section.

6AAE Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority

(1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:

(a) the function of including goods in the Register; or

(b) the power to include goods in the Register;

the officer or authority may include the goods in the Register in accordance with the corresponding State law.

(2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.

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(3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 6-1.

(4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers necessary to identify entries that relate to goods included in the Register under subsection (1).

(5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.

(6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:

(a) in the part of the Register for goods known as registered goods; or

(aa) in the part of the Register for goods known as provisionally registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(ba) in the part of the Register for biologicals included under Part 3-2A; or

(c) in the part of the Register for medical devices included under Chapter 4.

6B Review of certain decisions under State laws

(1) Application may be made to the Administrative Review Tribunal for review of a reviewable State decision.

(2) A decision made by the Secretary in the performance of a function, or the exercise of a power, conferred by a corresponding State law is a reviewable State decision for the purpose of this section if:

(a) the law under which the decision was made provides for review by the Administrative Review Tribunal; and

(b) the decision is declared by the regulations to be a reviewable decision for the purposes of this section.

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(3) For the purposes of subsection (1), the *Administrative Review Tribunal Act 2024* has effect as if a corresponding State law were an Act.

6C Fees payable to Commonwealth under State laws

(1) This section applies to fees payable to the Commonwealth under a State law in respect of the performance or exercise of functions or powers conferred by that law on the Secretary.

(2) The Secretary may make arrangements with the appropriate authority of a State, of the Australian Capital Territory or of the Northern Territory in relation to the payment to the Commonwealth of fees to which this section applies.

7 Declaration that goods are/are not therapeutic goods

(1) Where the Secretary is satisfied that classes of goods:

(a) are or are not therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods;

the Secretary may, by legislative instrument, make an order declaring that the classes of goods, or the classes of goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of this Act, therapeutic goods.

(1A) In deciding whether classes of goods:

(a) are therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are therapeutic goods;

the Secretary must disregard paragraphs (e) and (f) of the definition of ***therapeutic goods*** in subsection 3(1).

(4) If a declaration under this section:

(a) is a declaration that classes of goods are not therapeutic goods; and

(b) applies wholly or partly to goods that, apart from this section, would be medical devices;

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the goods are not medical devices, or are not medical devices when used, advertised, or presented for supply in the way specified in the declaration.

7AAA Minister may determine that goods are therapeutic goods

(1) The Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods (other than goods declared not to be therapeutic goods under an order in force under section 7 and goods covered by a determination under subsection 7AA(1) or (2) (excluded goods)):

(a) are therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are therapeutic goods.

(2) Before making a determination under subsection (1), the Minister:

(a) must have regard to the following matters:

(i) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;

(ii) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;

(iii) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme; and

(b) may have regard to any other relevant matter.

7AA Excluded goods

(1) The Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7) are excluded goods for the purposes of this Act.

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Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

(2) The Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7), when used, advertised, or presented for supply in a way specified in the determination, are excluded goods for the purposes of this Act.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

(3) Before making a determination under this section, the Minister must have regard to the following matters:

(a) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;

(b) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;

(c) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

(4) The Minister may have regard to any other matter he or she considers relevant.

7A Authorised persons

(1) The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act:

(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

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(iii) an authority of a State or of a Territory;
being a Department, unit or authority that
has functions relating to health matters or
law enforcement matters.

(2) In exercising a power under a provision of this Act under an authorisation under subsection (1), the authorised person must comply with any directions of the Secretary.

7B Kits

(1) If a package contains one or more goods, the package and each of the goods in the package together constitute a kit for the purposes of this Act if:

(a) the package and each of the goods are for use as a unit; and

(b) the package and the goods do not constitute a composite pack; and

(c) at least one of the goods is therapeutic goods; and

(d) each item of the therapeutic goods consists of goods that are:

(i) registered or listed; or

(ii) exempt goods in relation to Part 3-2; or

(iii) included in the Register under Part 3-2A; or

(iv) exempt under subsection 32CA(2) or section 32CB.

(2) A package and therapeutic goods in the package together constitute a composite pack if:

(a) the therapeutic goods are of 2 or more kinds; and

(b) the package does not contain any medical devices; and

(c) the therapeutic goods are for administration as a single treatment or as a single course of treatment; and

(d) it is necessary that the therapeutic goods be combined before administration or that they be administered in a particular sequence.

(3) To avoid doubt, it is declared that a kit constitutes therapeutic goods.

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7C Secretary may arrange for use of computer programs to make decisions

(1) The Secretary may arrange for the use, under the Secretary's control, of computer programs for any purposes for which the Secretary may make decisions under this Act or the regulations.

(2) A decision made by the operation of a computer program under such an arrangement is taken to be a decision made by the Secretary.

(3) The Secretary may substitute a decision (the ***substituted decision***) for a decision (the ***initial decision***) made by the operation of a computer program under such an arrangement if the Secretary is satisfied that the initial decision is incorrect.

(4) However, the substituted decision may only be made before the end of the period of 60 days beginning on the day the initial decision is made.

7D Form for product information for medicine

(1) The Secretary may, by writing, approve a form for product information in relation to medicine.

(2) The Secretary may approve different forms for different medicines or different classes of medicine.

8 Power to obtain information with respect to therapeutic goods

(1) The Secretary may, by notice in writing given to a person who has imported into Australia or has supplied in Australia:

(a) therapeutic goods; or

(b) goods in relation to which the Secretary is considering making a declaration under section 7; or

(ba) goods in relation to which the Minister is considering making a determination under subsection 7AAA(1) (goods that are therapeutic goods); or

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(c) goods in relation to which the Minister is considering making a determination under section 7AA (excluded goods);

request the person to give to an officer of the Department identified in the notice, within such reasonable period as is specified in the notice, information required by the notice concerning the composition, indications, directions for use or labelling of the goods or concerning advertising material relating to the goods.

(1A) A notice under subsection (1) may require the information to be given:

(a) in writing; or

(b) in accordance with specified software requirements:

(i) on a specified kind of data processing device; or

(ii) by way of a specified kind of electronic transmission.

(2) A person must not fail to comply with a notice given to the person under this section.

Penalty: 60 penalty units.

(3) Subsection (2) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (3). See subsection 13.3(3) of the *Criminal Code*.

(4) An offence under subsection (2) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

9 Arrangements with States etc.

(1) The Minister may make arrangements with the appropriate Minister of a State, of the Australian Capital Territory or of the Northern Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of:

(a) the evaluation of therapeutic goods for registration; or

(aa) the evaluation of a biological, other than a Class 1 biological or an export only biological, for inclusion in the Register under Part 3-2A; or

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(b) the inspection of manufacturers of therapeutic goods; or

(c) other functions under this Act or the regulations.

(2) An arrangement under this section may provide for the payment to a State or Territory of amounts in respect of the performance of functions under the arrangement.

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Chapter 2—Australian Register of Therapeutic Goods

9A Australian Register of Therapeutic Goods

(1) The Secretary is to cause to be maintained a register, to be known as the Australian Register of Therapeutic Goods, for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.

(2) Subject to subsection (3), the Register is to be kept in such form as the Secretary determines.

(3) The Register is to contain these 5 parts:

(a) a part for goods to be known as registered goods; and

(aa) a part for goods to be known as provisionally registered goods; and

(b) a part for goods to be known as listed goods; and

(ba) a part for biologicals included in the Register under Part 3-2A; and

(c) a part for medical devices included in the Register under Chapter 4.

(4) The regulations may prescribe:

(a) the therapeutic goods, or the classes of therapeutic goods, that are required to be included in each part of the Register; and

(b) the ways in which goods that are included in one part of the Register may be transferred, or may be required to be transferred, to another part of the Register; and

(c) the ways in which goods that have been assigned a registration or listing number may be assigned a different registration or listing number; and

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(ca) the ways in which a biological that has been assigned a number under subsection 32DB(2), 32DCB(2), 32DF(2) or 32DN(5) may be assigned a different number (which may be any combination of numbers and either or both of letters and symbols); and

(d) the ways in which medical devices that have been assigned a device number may be assigned a different device number.

9C Inspection of entries in Register

(1) A person in relation to whom therapeutic goods are entered on the Register may make a written request to the Secretary for a copy of the entry in the Register in relation to the goods.

(2) If the person makes such a request, the Secretary must send to the person a copy of so much (if any) of that entry as is contained in any computer database maintained by the Department for purposes connected with the administration of this Act (other than any part of that entry that was supplied in confidence by another person).

(3) If the person makes such a request, then, instead of providing a copy of an entry to the person, the Secretary may, if the request is for the provision of an electronic copy, provide the information contained in the entry:

(a) on a data processing device; or

(b) by way of electronic transmission.

9D Variation of entries in Register

(1) The Secretary may:

(a) following a request by a person in relation to whom therapeutic goods are entered on the Register; or

(b) on the Secretary's own initiative;

vary the entry in the Register in relation to the goods if the entry contains information that is incomplete or incorrect.

(1A) If:

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(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) it appears to the Secretary that the quality, safety or efficacy of the medicine is unacceptable in relation to a class of persons;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine:

(c) to reduce the class of persons for whom the medicine is suitable or to change the directions for use; or

(d) to add a warning, or precaution, that does not include any comparison of the medicine with any other medicine by reference to quality, safety or efficacy.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

(1B) If:

(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) the Secretary makes a decision under subsection 29(9) to extend the provisional registration period for the medicine;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine to reduce the class of persons for whom the medicine is suitable or to change the directions for use.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

(1C) If the Secretary proposes to make a variation under subsection (1A) or (1B), the Secretary must:

(a) give the person in relation to whom the medicine is registered written notice of the proposed variation and of the reasons for the proposed variation; and

(b) give the person a reasonable opportunity to make a submission to the Secretary in relation to the proposed variation; and

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(c) if the person makes a submission in accordance with paragraph (b)—take the submission into account before making a decision whether or not to make the variation.

(1D) Subsections (1A) and (1B) apply despite subsection 16(1).

(2) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary information included in the entry in the Register that relates to the goods; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the goods are suitable; or

(ii) to add a warning, or precaution, that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;

the Secretary must vary the entry in accordance with the request.

(2A) Subsection (2), to the extent to which it relates to subparagraph (2)(b)(i), applies despite subsection 16(1).

(2C) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary the entry in the Register that relates to the goods; and

(b) the variation is of a kind specified in the regulations; and

(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(2D) Subsection (2C), to the extent that it relates to therapeutic goods that are registered, applies despite subsection 16(1).

(3) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary

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information included in the entry in the Register that relates to the goods; and

(b) subsection (2) does not apply to the request; and (ba) subsection (2C) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used;

the Secretary may vary the entry in accordance with the request.

(3AA) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the biological; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the biological is suitable; or

(ii) to add a warning, or precaution, that does not include any comparison of the biological with any other therapeutic goods by reference to quality, safety or efficacy;

the Secretary must vary the entry in accordance with the request.

(3AC) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary the entry in the Register that relates to the biological; and

(b) the variation is of a kind specified in the regulations; and

(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(3A) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the biological; and

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(aa) subsection (3AA) does not apply to the request; and (ab) subsection (3AC) does not apply to the request; and

(b) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the biological for the purposes for which it is to be used;

the Secretary may vary the entry in accordance with the request.

(3B) If:

(a) a particular biological ceases to be a biological because of a determination under subsection 32A(3); and

(b) the biological is included in the Register under Part 3-2A;

the Secretary must move the entry relating to the biological from the part of the Register for biologicals to whichever other part of the Register is applicable.

(3C) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the kind of medical device; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the kind of medical device is suitable; or

(ii) to add a warning, restriction or precaution, that does not include any comparison of the kind of medical device with any other therapeutic goods by reference to quality, safety or performance;

the Secretary must vary the entry in accordance with the request.

(3CB) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary the entry in the Register that relates to the kind of medical device; and

(b) the variation is of a kind specified in the regulations; and

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(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(3D) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the kind of medical device; and

(b) subsection (3C) does not apply to the request; and

(ba) subsection (3CB) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or performance of the kind of medical device for the purposes for which it is to be used;

the Secretary may vary the entry in accordance with the request.

(4) If:

(a) particular therapeutic goods cease to be medical devices because of a declaration under subsection 41BD(3); and

(b) those goods are included in the Register under Chapter 4 as a kind of medical device;

the Secretary must move the entry relating to the goods from the part of the Register for medical devices to whichever other part of the Register is applicable.

Note: Variations to the Register also occur to give effect to limited cancellations of entries of kinds of medical devices from the Register:
see subsection 41GO(2).

Form and manner of requests

(6) The Secretary may, by writing:

(a) approve a form for particular kinds of requests under this section; and

(b) approve the manner of making particular kinds of requests under this section.

(7) If:

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(a) the Secretary has approved a form for, and the manner of making, a kind of request under this section; and

(b) either:

(i) the kind of request is one under subsection (3) and which, under the regulations, must be decided within 175 or 255 working days; or

(ii) the kind of request is one prescribed by the regulations for the purposes of this subparagraph;

then a request of that kind is not effective unless:

(c) the request is in accordance with that form; and

(d) the request contains the information required by that form; and

(e) the request is made in that manner; and

(f) any prescribed application fee has been paid; and

(g) the request is accompanied by information that is:

(i) of a kind determined under subsection (8); and

(ii) in a form approved, in writing, by the Secretary.

(8) The Secretary may, by legislative instrument, determine a kind of information for the purposes of subparagraph (7)(g)(i).

Note: See also subsection 33(3A) of the *Acts Interpretation Act 1901*.

9E Publication of list of goods on Register

The Secretary must, at least once every 12 months, publish a list of the therapeutic goods included in the Register.

9F Removal of entries from Register

(1) This section applies if:

(a) there is an entry on the Register in relation to goods; and

(b) the Secretary is satisfied that the goods are not therapeutic goods.

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(2) The Secretary may, by written notice given to the person in relation to whom the goods are entered on the Register, remove the entry of the goods from the Register.

(3) Before removing the entry, the Secretary must:

(a) inform the person in writing that the Secretary proposes the removal and set out the reasons for it; and

(b) invite the person to make written submissions to the Secretary in relation to the proposed removal within the period specified in the notice (being not less than 20 working days after the day the notice is given).

(4) The Secretary must not give the person a notice under subsection (2) until the Secretary has had regard to any submissions the person makes under paragraph (3)(b).

(5) A notice under subsection (2) is not a legislative instrument.

(6) If the Secretary removes an entry of goods from the Register under this section, the removal has effect on the day specified in the notice under subsection (2) in relation to the goods, being a day not earlier than 20 working days after the day on which the notice is given to the person.

(7) If the Secretary removes an entry of goods from the Register under this section, the Secretary must, as soon as practicable after the removal, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the removal.

9G Criminal offences for false statements in requests for variation of entries in Register

(1) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

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(c) the statement is false or misleading in a material particular; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(4) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

(c) the statement is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

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9H Civil penalty for false statements in requests for variation of entries in Register

A person contravenes this section if the person in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods, makes a statement that is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Chapter 2A—Prohibition on import, export, manufacture or supply of therapeutic goods or vaping goods—international agreements

9J Simplified outline of this Chapter

The regulations may prohibit imports into Australia, exports from Australia, the manufacture in Australia and supplies in Australia of therapeutic goods or vaping goods, or therapeutic goods or vaping goods containing a particular ingredient or component, to give effect to international agreements to which Australia is a party.

There is an offence and a civil penalty for contravening such a prohibition.

9K Prohibition on import, export, manufacture or supply of therapeutic goods or vaping goods—international agreements

Prohibition on therapeutic goods or vaping goods themselves

(1) If therapeutic goods or vaping goods are the subject of an international agreement prescribed for the purposes of this subsection, the regulations may prohibit one or more of the following:

(a) the import into Australia of the therapeutic goods or vaping goods;

(b) the export from Australia of the therapeutic goods or vaping goods;

(c) the manufacture in Australia of the therapeutic goods or vaping goods;

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(d) the supply in Australia of the therapeutic goods or vaping goods.

(2) Before regulations are made prescribing an international agreement for the purposes of subsection (1), the Minister must be satisfied that the agreement requires parties to the agreement to take steps to prohibit or restrict one or more of the import, export, manufacture and supply of certain goods.

Prohibition on therapeutic goods or vaping goods containing an ingredient or component

(3) If an ingredient or component of therapeutic goods or vaping goods is the subject of an international agreement prescribed for the purposes of this subsection, the regulations may prohibit one or more of the following:
(a) the import into Australia of all or specified therapeutic goods or vaping goods that contain that ingredient or component;
(b) the export from Australia of all or specified therapeutic goods or vaping goods that contain that ingredient or component;
(c) the manufacture in Australia of all or specified therapeutic goods or vaping goods that contain that ingredient or component;
(d) the supply in Australia of all or specified therapeutic goods or vaping goods that contain that ingredient or component.

(4) Before regulations are made prescribing an international agreement for the purposes of subsection (3), the Minister must be satisfied that the agreement requires parties to the agreement to take steps to prohibit or restrict one or more of the import, export, manufacture and supply of goods containing that ingredient or component. *Nature of prohibition*

(5) A prohibition referred to in subsection (1) or (3) may be absolute or be subject to such conditions as are prescribed.

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Procedural requirements for regulations containing prohibition

(6) Regulations containing a prohibition referred to in subsection (1) or (3) must not be made unless:

(a) the Minister causes to be published on the Department's website a notice setting out details of:

(i) the international agreement; and

(ii) the Minister's satisfaction mentioned in subsection (2) or (4); and

(iii) the proposed prohibition; and

(b) a period of 30 days has passed since the notice was published.

Commencement of regulations containing prohibition

(7) Regulations containing a prohibition referred to in subsection (1) or (3) must not be expressed to commence on a day earlier than the day the international agreement enters into force for Australia. *Content of regulations containing prohibition*

(8) Without limiting subsection (5), regulations prescribing conditions referred to in that subsection may do one or more of the following:

(a) make provision in relation to a matter by conferring on the Minister or Secretary a power to make a decision of an administrative character;

(b) refer to the Minister or Secretary being satisfied of one or more specified matters;

(c) make provision for and in relation to the Minister or Secretary delegating powers to an SES employee, or acting SES employee, in the Department.

9L Offence and civil penalty

Offence

(1) A person commits an offence if:

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(a) the person:

(i) imports into Australia therapeutic goods or vaping goods; or

(ii) exports from Australia therapeutic goods or vaping goods; or

(iii) manufactures in Australia therapeutic goods or vaping goods; or

(iv) supplies in Australia therapeutic goods or vaping goods; and

(b) the import, export, manufacture or supply contravenes:

(i) an absolute prohibition in force for the purposes of subsection 9K(1) or (3); or

(ii) one or more conditions of a prohibition in force for the purposes of subsection 9K(1) or (3).

Penalty: 300 penalty units.

Civil penalty

(2) A person contravenes this subsection if:

(a) the person:

(i) imports into Australia therapeutic goods or vaping goods; or

(ii) exports from Australia therapeutic goods or vaping goods; or

(iii) manufactures in Australia therapeutic goods or vaping goods; or

(iv) supplies in Australia therapeutic goods or vaping goods; and

(b) the import, export, manufacture or supply contravenes:

(i) an absolute prohibition in force for the purposes of subsection 9K(1) or (3); or

(ii) one or more conditions of a prohibition in force for the purposes of subsection 9K(1) or (3).

Maximum civil penalty:

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(a) for an individual—300 penalty units; and
(b) for a body corporate—3,000 penalty units.

9M Application of *Customs Act 1901*

If:

(a) the importation or exportation of goods is an offence under subsection 9L(1) or a contravention of subsection 9L(2); and
(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or
(d) prohibited exports within the meaning of that Act; as the case requires.

9N Constitutional basis

(1) This Chapter, and any other provision of this Act to the extent it relates to this Chapter, relies on the Commonwealth's legislative power under paragraph 51(xxix) of the Constitution to give effect to an international agreement prescribed for the purposes of subsection 9K(1) or (3).

(2) This section does not limit section 6.

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Chapter 3—Medicines and other therapeutic goods that are not medical devices

Part 3-1—Standards

10 Determination of standards

(1) The Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia).

Note: Section 12 of the *Legislation Act 2003* deals with when a legislative instrument commences.

(2) Without limiting the generality of subsection (1), an order establishing a standard for therapeutic goods may:

(a) be specified by reference to:

(i) the quality of the goods; or

(ii) the quantity of the goods when contained in specified containers; or

(iii) procedures to be carried out in the manufacture of the goods; or

(iv) a monograph in the British Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia; or

(v) a monograph in another publication approved by the Minister for the purposes of this subsection; or

(vi) such a monograph as modified in a manner specified in the order establishing the standard; or

(vii) a standard published by Standards Australia; or

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(viii) such other matters as the Minister thinks fit; or

(b) require that a matter relating to the standard be determined in accordance with a particular test; or

(c) require that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

(3) Without limiting the generality of paragraph (2)(c), the Minister may, in an order establishing a standard, direct that there be set out, in a manner specified in the order, on:

(a) therapeutic goods or a class of therapeutic goods identified in the order; or

(b) a container or package containing therapeutic goods or a class of therapeutic goods identified in the order; or

(c) a label of therapeutic goods or a class of therapeutic goods identified in the order;

such particulars as are required by the order.

(3A) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

Note: Section 12 of the *Legislation Act 2003* deals with when a legislative instrument commences.

(4) Despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection (1) of this section, or a variation of such an order, may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

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13 Special provisions relating to Ministerial standards and default standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary refers to a statement in a monograph in another publication, the main statement is taken to include the other statement.

(2) If:

(a) a standard under section 10 (the ***Ministerial standard***) applies to therapeutic goods; and

(b) requirements applicable to the goods are specified in a default standard; and

(c) those requirements are inconsistent with the requirements specified in the Ministerial standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

(3) If:

(a) a default standard applies to a class of therapeutic goods; and

(b) another default standard applies to only some of the therapeutic goods within that class; and

(c) those standards are inconsistent;

the standard referred to in paragraph (a) does not apply in relation to the goods referred to in paragraph (b).

(4) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) a default standard is applicable to one or more of the ingredients or one or more of the component parts; and

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(c) a default standard is applicable to the mixture or combination;

the standard referred to in paragraph (b) does not apply in relation to the goods.

(5) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) there is no standard applicable to the mixture or combination but a standard is applicable to one or more of the ingredients or one or more of the component parts;

the Minister may, by order published in the *Gazette* or on the Department's website, determine that the standard does not apply to the goods. The order has effect accordingly.

(6) An order under subsection (5) is not a legislative instrument.

(7) For the purposes of this Act, in working out at a particular time if therapeutic goods conform with a default standard applicable to the goods, if:

(a) after applying subsections (2) to (5), 2 or more default standards are applicable to the goods at that time; and

(b) at that time, the goods conform with at least one of those standards but do not conform with at least one of those standards;

then the default standards that the goods do not conform with are taken not to apply to the goods at that time.

13A Special provisions relating to homoeopathic standards and anthroposophic standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia refers to a statement in a monograph in another publication, the main statement is taken to include the other statement.

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(2) If:

(a) a standard under section 10 (the ***Ministerial standard***) applies to therapeutic goods; and

(b) requirements applicable to the goods are specified in a homoeopathic standard or an anthroposophic standard; and

(c) those requirements are inconsistent with the requirements specified in the Ministerial standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

14 Criminal offences for importing, supplying or exporting goods that do not comply with standards

Offences relating to importing goods into Australia

(1) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging); and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the goods do not conform with the standard.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Exception

(5A) Subsection (1), (4) or (4A) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person imports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5A): see subsection 13.3(3) of the *Criminal Code*.

Offences relating to supplying goods for use in Australia

(6) A person commits an offence if:

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(a) the person supplies therapeutic goods for use in Australia; and
(b) the goods are supplied without the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods; and
(d) either:
(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and
(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the goods do not conform with the standard.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (9) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(9) A person commits an offence if:
(a) the person supplies therapeutic goods for use in Australia; and
(b) the goods are supplied without the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(9AA) A person commits an offence if:
(a) the person supplies therapeutic goods for use in Australia; and

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(b) the goods are supplied without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods.

Penalty: 100 penalty units.

(9AB) An offence against subsection (9AA) is an offence of strict liability.

Exception

(9A) Subsection (6), (9) or (9AA) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person supplies the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Note: A defendant bears an evidential burden in relation to the matter in subsection (9A): see subsection 13.3(3) of the *Criminal Code*.

Offences relating to exporting goods from Australia

(10) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia); and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the goods do not conform with the standard.

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Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (13) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(13) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(13AA) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Penalty: 100 penalty units.

(13AB) An offence against subsection (13AA) is an offence of strict liability.

Exception

(13A) Subsection (10), (13) or (13AA) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person exports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

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Note: A defendant bears an evidential burden in relation to the matter in subsection (13A): see subsection 13.3(3) of the *Criminal Code*.

Decisions on whether to give consent

(14) The Secretary must, as soon as practicable after making a decision to give a consent, cause particulars of the decision to be published in the *Gazette* or on the Department's website.

(15) The Secretary must, within 28 days after making a decision to refuse to give a consent, notify the applicant in writing of the decision and of the reasons for the decision.

(16) The Secretary is not required to consider giving an applicant a consent unless the applicant has paid the fee that is prescribed by the regulations for the processing of the applicant's application for a consent.

14A Civil penalties for importing, supplying or exporting goods that do not comply with standards

Civil penalty relating to importing goods into Australia

(1) A person contravenes this subsection if:

(a) the person imports therapeutic goods into Australia; and

(b) the person does not have the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception

(1A) Subsection (1) does not apply if:

(a) the therapeutic goods are a biological; and

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(b) the person imports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Civil penalty relating to supplying goods for use in Australia

(2) A person contravenes this subsection if:

(a) the person supplies therapeutic goods for use in Australia; and

(b) the person does not have the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception

(2A) Subsection (2) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person supplies the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Civil penalty relating to exporting goods from Australia

(3) A person contravenes this subsection if:

(a) the person exports therapeutic goods from Australia; and

(b) the person does not have the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

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(b) for a body corporate—50,000 penalty units.

Exception

(3A) Subsection (3) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person exports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Decisions on whether to give consent

(4) The Secretary must, as soon as practicable after making a decision to give a consent, cause particulars of the decision to be published in the *Gazette* or on the Department's website.

(5) The Secretary must, within 28 days after making a decision to refuse to give a consent, notify the applicant in writing of the decision and of the reasons for the decision.

(6) The Secretary is not required to consider giving an applicant a consent unless the applicant has paid the fee that is prescribed by the regulations for the processing of the applicant's application for a consent.

14B Application of *Customs Act 1901*

Where:

(a) the importation or exportation of goods is an offence under subsection 14(1), (4), (4A), (10), (13) or (13AA) or 41Q(1) or (2) or a contravention of subsection 14A(1) or (3) or 41Q(3); and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

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(c) prohibited imports within the meaning of that Act; or
(d) prohibited exports within the meaning of that Act; as the case requires.

15 Criminal offences relating to breaching a condition of a consent

(1) The consent of the Secretary under section 14 or 14A may be given:
(a) unconditionally or subject to conditions; or
(b) in respect of particular goods or classes of goods.

(2) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent; and
(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (5) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(5) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent.

Penalty: 500 penalty units.

(6) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent.

Penalty: 100 penalty units.

(7) An offence against subsection (6) is an offence of strict liability.

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15AA Civil penalty relating to breaching a condition of a consent

A person contravenes this section if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a condition of a consent imposed under section 15.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

15AB Conditions relating to exceptional release of biologicals

(1) Regulations made for the purposes of paragraphs 14(9A)(b) and 14A(2A)(b) may also prescribe conditions that apply in relation to the supply of a biological that occurs after the circumstances prescribed for the purposes of those paragraphs have occurred.

(2) The conditions prescribed by those regulations must apply only to the person supplying the biological.

(3) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission results in the breach of any of the conditions referred to in subsection (1).

Penalty for contravention of this subsection:60 penalty units.

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Part 3-2—Registration and listing of therapeutic goods

Division 1—Preliminary

15A Part does not apply to a medical device

This Part does not apply to a medical device.

Note: Chapter 4 deals with medical devices.

15B Application of this Part to a biological

(1) Subject to this section, this Part does not apply to a biological on and after the commencement of this section.

Biologicals currently included in the Register

(2) If, immediately before the commencement of this section, therapeutic goods that are a biological were registered goods or listed goods, this Part continues to apply to the biological on and after that commencement until the time the biological is included in the Register under Part 3-2A.

Note: Section 32DN deals with including the biological under Part 3-2A.

Pending applications

(3) If:

(a) before the commencement of this section, an application was made under this Part for the registration or listing of therapeutic goods that are a biological; and

(b) immediately before that commencement, the application was not finally determined; and

(c) the application had not been withdrawn before that commencement;

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this Part continues to apply to the biological on and after that commencement until the earliest of the following:

(d) the time the biological is included in the Register under Part 3-2A;

(e) if the application is unsuccessful when it is finally determined—the time the application is finally determined;

(f) the time the application is withdrawn;

(g) the time the application lapses.

Note: Section 32DN deals with including the biological under Part 3-2A.

(4) For the purposes of this section, an application is ***finally determined*** when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

Transitional

(5) This Part applies to a biological on and after the commencement of this section in relation to things done, or omitted to be done, in relation to the biological before the commencement of this section.

(6) If this Part continues to apply to a biological during a period described in subsection (2) or (3), then this Part also applies to the biological after the end of that period in relation to things done, or omitted to be done, in relation to the biological during that period.

16 Therapeutic goods and gazetted groups

(1) For the purposes of this Part, therapeutic goods (other than medicine of the kind to which subsection (1A) applies) are to be taken to be separate and distinct from other therapeutic goods if they have:

(a) a different formulation, composition or design specification; or

(b) a different strength or size (disregarding pack size); or

(c) a different dosage form or model; or

(d) a different name; or

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(e) different indications; or

(f) different directions for use; or

(g) a different type of container (disregarding container size).

(1A) Medicines that are listable goods (other than export only medicines) are taken to be separate and distinct from other therapeutic goods if the medicines have:

(a) different active ingredients; or

(b) different quantities of active ingredients; or

(c) a different dosage form; or

(d) such other different characteristics as the regulations prescribe;

from the therapeutic goods.

(2) The Secretary may, by order published in the *Gazette*, determine that a group of therapeutic goods (not being medical devices) identified in the order is a gazetted therapeutic goods group because the goods within the group have common characteristics.

(3A) The Secretary may, by order published in the *Gazette*, determine that a group of kits identified in the order is a gazetted kits group.

(4) An order under subsection (2) or (3A) may make provision for or in relation to a matter by applying, adopting or incorporating, with or without modification, a document as in force from time to time, if the document is:

(a) published by the Department (whether in electronic form or otherwise); and

(b) available for sale to the public; and

(c) available for inspection (whether by using a visual display unit or otherwise) by the public at offices of the Department specified by the Secretary.

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18 Exempt goods

(1) The regulations may, subject to such conditions (if any) as are specified in the regulations, exempt:

(a) all therapeutic goods, except those included in a class of goods prescribed for the purposes of this paragraph; or

(b) specified therapeutic goods; or

(c) a specified class of therapeutic goods;

from the operation of this Part (except section 31A and sections 31C to 31F).

(2) An exemption in terms of paragraph (1)(a) has effect only in relation to such classes of persons as are prescribed for the purposes of this subsection.

(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, specified in the regulations.

18A Exemption because of emergency

Minister's power

(1) The Minister may exempt from the operation of Division 2 of this Part:

(a) specified therapeutic goods; or

(b) therapeutic goods in a specified class.

The exemption must be made in writing.

(1A) The Minister may exempt goods under subsection (1) only if the Minister is satisfied of the matter in subsection (2) or (2A).

(2) The matter in this subsection is that in the national interest:

(a) the exemption should be made so that the goods may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency; or

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(b) the exemption should be made so that the goods can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred.

(2A) The matter in this subsection is that:

(a) a national emergency declaration is in force; and

(b) either of the following apply:

(i) the exemption should be made so that the goods may be stockpiled to deal with a potential threat to public health that may be caused by the emergency to which the national emergency declaration relates;

(ii) the exemption should be made so that the goods can be made available urgently in Australia in order to deal with an actual threat to public health caused by the emergency to which the national emergency declaration relates; and

(c) the Minister is satisfied that the exemption is in the national interest.

When the exemption has effect

(3) The exemption takes effect:

(a) on the day on which the exemption is made; or

(b) on a later day that is specified in the exemption.

(4) The exemption ceases to have effect:

(a) at the end of the period specified by the Minister in the exemption as the period for which the exemption is to have effect; or

(b) when the exemption is revoked;

whichever first occurs.

(5) The exemption ceases to have effect in relation to particular therapeutic goods:

(a) when those goods become registered or listed goods; or

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(b) when the Minister varies the exemption by removing those goods from the exemption;

whichever first occurs.

(6) If the Minister revokes the exemption as mentioned in paragraph (4)(b), or varies the exemption as mentioned in paragraph (5)(b), the revocation or variation takes effect:

(a) if the Minister states in the revocation or variation that the revocation or variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the revocation or variation is made; or

(b) in any other case—on the day specified by the Minister in the revocation or variation.

The day specified under paragraph (b) of this subsection must not be earlier than 28 days after the day on which the revocation or variation is made.

Note: The revocation or variation must be made in writing, see subsection 33(3) of the *Acts Interpretation Act 1901*.

Conditions for the exemption

(7) The exemption is subject to conditions specified in the exemption about any of the following:

(a) the period for which the exemption is to have effect;

(b) the quantity of goods that are exempt;

(c) the source of those goods;

(d) the persons or class of persons who may import, manufacture, supply or export those goods;

(e) the supply of those goods (including the persons or class of persons to whom goods may be supplied for use and the circumstances under which a stockpile of goods may be supplied for use);

(f) the storage and security of those goods;

(g) the keeping and disclosure of, and access to, records about those goods;

(h) the disposal of those goods;

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(i) the manner in which any of those goods are to be dealt with if a condition of the exemption is breached;

(j) any other matters that the Minister thinks appropriate.

Whether or not goods are exempt under this section is not affected by whether or not there is a breach of a condition of an exemption under this section in relation to those goods.

Note 1: A person may commit an offence by breaching a condition of an exemption under this section, see subsections 20(2A) and (2C), 22(7AB) and (7AD), and 30H(1) and (3).

Note 2: A person may also contravene a civil penalty provision, see section 22AA.

(8) The Minister may revoke or vary the conditions (including by imposing new conditions) after the exemption is made. The revocation or variation must be made in writing.

(9) A revocation or variation under subsection (8) takes effect:

(a) if the Minister states in the revocation or variation that the revocation or variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the revocation or variation is made; or

(b) in any other case—on the day specified by the Minister in the revocation or variation.

The day specified under paragraph (b) must not be earlier than 28 days after the day on which the revocation or variation is made.

Exemption not a legislative instrument

(9A) An exemption under subsection (1) is not a legislative instrument.

Informing persons of exemption etc.

(9B) If the Minister makes an exemption under subsection (1), the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph (7)(d):

(a) the exemption;

(b) any revocation or variation of the exemption under this section.

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Notification

(10) The Secretary must cause a document setting out particulars of:

(a) an exemption covered by paragraph (2)(b) or subparagraph (2A)(b)(ii); and

(b) a revocation or variation under this section of an exemption covered by paragraph (2)(b) or subparagraph (2A)(b)(ii);

to be published in the *Gazette* within 5 working days after the day on which the Minister makes the exemption, revocation or variation. However, an exemption, or a revocation or variation, is not invalid merely because of a failure to comply with this subsection.

Tabling

(11) The Minister must cause a document setting out particulars of:

(a) an exemption covered by paragraph (2)(b) or subparagraph (2A)(b)(ii); and

(b) a revocation or variation under this section of an exemption covered by paragraph (2)(b) or subparagraph (2A)(b)(ii);

to be tabled before each House of the Parliament within 5 sitting days of that House after the day on which the Minister makes the exemption, revocation or variation. However, an exemption, or a revocation or variation, is not invalid merely because of a failure to comply with this subsection.

Note: There are other requirements in other parts of this Act about goods exempt under this section:

(a) sections 20, 22 and 22AA (breach of a condition of the exemption);

(b) sections 30F and 30FA (goods not conforming to standards etc.);

(c) section 30G (disposal of unused goods);

(d) section 30H (record keeping);

(e) section 31AA (providing information to the Secretary);

(f) sections 35, 35A, 39 and 41 (manufacturing goods that are exempt under this section);

(g) section 46A (search of premises).

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19 Approvals or authorities for certain uses

(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into, or the exportation from, Australia or the supply in Australia of specified therapeutic goods that are not registered goods or listed goods:

(a) for use in the treatment of another person; or

(b) for use solely for experimental purposes in humans;

and such an approval may be given subject to such conditions as are specified in the notice of approval.

Note: For variation of an approval for use of the kind referred to in paragraph (1)(b), see subsection (4B).

(1AA) An approval for use of the kind referred to in paragraph (1)(a) must not be granted to a person unless the person is a health practitioner.

(1A) An approval mentioned in paragraph (1)(a) or (b) is subject to the conditions (if any) specified in the regulations for the purposes of that paragraph. Those conditions (if any) are in addition to any conditions imposed on the approval under subsection (1).

(2) An application for an approval must be made to the Secretary and must:

(a) in the case of an application for use of the kind referred to in paragraph (1)(a)—be in a form (if any) approved, in writing, by the Secretary and be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and

(b) in the case of an application for use of the kind referred to in paragraph (1)(b):

(i) be in a form (if any) approved, in writing, by the Secretary; and

(ii) be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and

(iii) be accompanied by the prescribed evaluation fee.

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(3) Without limiting the conditions to which an approval under subsection (1) may be made subject, those conditions may include a condition relating to the charges that may be made for the therapeutic goods to which the approval relates.

(4) Where an application for an approval is made, the Secretary must, after having considered the application and, in the case of an application for the use of therapeutic goods for experimental purposes in humans, after having evaluated the information submitted with the application, notify the applicant of the decision on the application within 28 days of making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

(4A) The use by a person for experimental purposes in humans of specified therapeutic goods that are the subject of an approval granted to someone else under paragraph (1)(b) is subject to the conditions (if any) specified in the regulations relating to one or more of the following:

(a) the preconditions on the use of the goods for those purposes;

(b) the principles to be followed in the use of the goods for those purposes;

(c) the monitoring of the use, and the results of the use, of the goods for those purposes;

(d) the circumstances in which the person must cease the use of the goods for those purposes.

(4B) If:

(a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(b); and

(b) the person requests the Secretary to do either or both of the following:

(i) vary the therapeutic goods specified in the approval;

(ii) vary the conditions imposed under subsection (1) on the approval; and

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(c) the request is in a form (if any) approved, in writing, by the Secretary; and

(d) the request is accompanied by such information relating to the therapeutic goods as is required by the Secretary; and

(e) the request is accompanied by the fee prescribed by the regulations;

the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation requested and may involve imposing new conditions on the approval or varying or removing existing conditions.

(4C) The Secretary must notify the person making the request under subsection (4B) of:

(a) the Secretary's decision on the request; and

(b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.

(4D) A variation under subsection (4B) takes effect at the time the Secretary notifies the person under subsection (4C) of the variation.

(5) The Secretary may, in writing, authorise a specified medical practitioner to supply:

(a) specified therapeutic goods for use in the treatment of humans; or

(b) a specified class of such goods;

to the class or classes of recipients specified in the authority.

(5AA) An application for an authority under subsection (5) must be in a form (if any) approved, in writing, by the Secretary.

(5A) An authority may be given subject to the conditions (if any) specified in the authority.

(5B) The Secretary may impose conditions (or further conditions) on an authority given to a person under subsection (5) by giving to the person written notice of the conditions (or further conditions).

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(6) An authority under subsection (5) may only be given:

(a) to a medical practitioner included in a class of medical practitioners prescribed by the regulations for the purposes of this paragraph; and

(aa) to a medical practitioner who has the approval of an ethics committee to supply the specified therapeutic goods or the specified class of such goods; and

(b) in relation to a class or classes of recipients prescribed by the regulations for the purposes of this paragraph.

Paragraph (aa) does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection.

(7) The regulations may prescribe the circumstances in which therapeutic goods may be supplied under an authority under subsection (5).

(7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply:

(a) specified therapeutic goods for use in the treatment of humans; or

(b) a specified class of such goods;

to the class or classes of recipients specified in those rules, so long as:

(c) the goods are supplied in the circumstances specified in those rules; and

(d) the conditions (if any) specified in those rules are satisfied.

(7B) In making rules under subsection (7A), the Minister must comply with:

(a) such requirements (if any) as are prescribed by the regulations; and

(b) such restrictions (if any) as are prescribed by the regulations; and

(c) such limitations (if any) as are prescribed by the regulations.

(7C) If:

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(a) a person is authorised, by subsection (7A) rules, to supply therapeutic goods; and

(b) the person supplies those goods in accordance with those rules;

the person must:

(c) notify the supply to the Secretary; and

(d) do so within 28 days after the supply.

(7D) A notification under subsection (7C) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain such information as is prescribed by the regulations.

(7E) An approval of a form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(7F) A person commits an offence if:

(a) the person is subject to a requirement under subsection (7C); and

(b) the person omits to do an act; and

(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(7G) An offence against subsection (7F) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of therapeutic goods if a health practitioner, on behalf of the person, does the following:

(a) notifies the supply to the Secretary within 28 days after the supply;

(b) makes the notification in accordance with the requirements referred to in subsection (7D).

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Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

(7H) In recommending to the Governor-General that regulations should be made for the purposes of paragraph (7D)(b), the Minister must have regard to the principle that information should only be prescribed for the purposes of that paragraph if the information is reasonably required for the responsible scrutiny by the Secretary of the operation of the scheme embodied in subsection (7A).

(8) The regulations may prescribe the circumstances in which an approval under paragraph (1)(a), or an authority under subsection (5), must not be given, including but not limited to, circumstances relating to the following:

(a) therapeutic goods included in a specified class;

(b) therapeutic goods when used in the treatment of a specified class of persons;

(c) therapeutic goods when used for a particular indication.

19A Approvals where unavailability etc. of therapeutic goods

(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods:

(i) are unavailable or are in short supply; or

(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

(b) either:

(i) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); or

(ii) an application under section 23 has been made for registration of the goods and the application has passed preliminary assessment; and

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(c) the goods are of a kind:

(i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or

(ii) specified by the Secretary in a determination under subsection (4); and

(d) the approval is necessary in the interests of public health.

(1A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods:

(i) are unavailable or are in short supply; or

(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

(b) either:

(i) the goods that are the subject of the application are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3); or

(ii) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3), but are not readily available for importation into, and supply in, Australia; and

(c) the goods are registered or approved for general marketing in a foreign country; and

(d) the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and

(e) the goods are of a kind:

(i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or

(ii) specified by the Secretary in a determination under subsection (4); and

(f) the approval is necessary in the interests of public health.

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(2) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods do not exist; and

(b) an application under section 23 has been made for registration of the goods; and

(ba) the application has passed preliminary assessment; and

(c) the goods are of a kind:

(i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or

(ii) specified by the Secretary in a determination under subsection (4); and

(d) the approval is necessary in the interests of public health.

(2A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods (the ***subject goods***) if the Secretary is satisfied:

(a) that there are no registered goods that could act as a substitute for the subject goods; and

(b) either:

(i) that previously registered goods could act as a substitute for the subject goods; or

(ii) that therapeutic goods whose registration is suspended under section 29D could act as a substitute for the subject goods; and

(c) that the subject goods are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); and

(d) that the subject goods are of a kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; and

(e) that the approval is necessary in the interests of public health.

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(2B) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods (the ***subject goods***) if the Secretary is satisfied:

(a) that there are no registered goods that could act as a substitute for the subject goods; and

(b) either:

(i) that previously registered goods could act as a substitute for the subject goods; or

(ii) that therapeutic goods whose registration is suspended under section 29D could act as a substitute for the subject goods; and

(c) that all of the following apply:

(i) the subject goods are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3);

(ii) the subject goods are registered or approved for general marketing in at least one foreign country that is not specified by the Secretary in a determination under subsection (3);

(iii) the manufacturing and quality control procedures used in the manufacture of the subject goods are acceptable; and

(d) that the subject goods are of a kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; and

(e) that the approval is necessary in the interests of public health.

(3) The Secretary may make written determinations specifying foreign countries for the purposes of this section.

(4) The Secretary may make written determinations specifying the kinds of goods that can be the subject of an approval under this section.

(5) Determinations under subsections (3) and (4) are legislative instruments.

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(6) The Secretary may grant the approval subject to any conditions that are specified in the notice of approval.

(7) The Secretary may grant the approval for such period as is specified in the notice of approval.

(8) The approval lapses if:

(a) the period specified in the notice of approval expires; or

(b) a decision has been made under subsection 25(3) in relation to the goods.

(9) The approval lapses if:

(a) the Secretary is satisfied that paragraph (1)(a), (b), (c) or (d), paragraph (1A)(a), (b), (c), (d), (e) or (f), paragraph (2)(a), (b), (ba), (c) or (d), paragraph (2A)(a), (b), (c), (d) or (e) or paragraph (2B)(a), (b), (c), (d) or (e), as the case requires, no longer applies in relation to the goods, or that a condition of the approval has been contravened; and

(b) the Secretary has given to the person to whom the approval was granted a notice stating that the Secretary is so satisfied.

(10) The lapsing of the approval on the expiry of the period specified in the notice of approval does not prevent another approval being granted under this section in relation to the goods before the lapsing of the first-mentioned approval. The other approval may be expressed to take effect on the expiry of that period.

(11) An approval under subsection (1), (1A), (2), (2A) or (2B) is not a legislative instrument.

19B Criminal offences relating to registration or listing etc. of imported, exported, manufactured and supplied therapeutic goods

Offences relating to importing, exporting, manufacturing or supplying goods for use in humans

(1) A person commits an offence if:

(a) the person:

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(i) imports into Australia therapeutic goods for use in humans; or
(ii) exports from Australia therapeutic goods for use in humans; or
(iii) manufactures in Australia therapeutic goods for use in humans; or
(iv) supplies in Australia therapeutic goods for use in humans; and
(b) none of the following subparagraphs applies in relation to the goods:
(i) the goods are registered goods or listed goods in relation to the person;
(ii) the goods are exempt goods;
(iii) the goods are exempt under section 18A;
(iv) the goods are the subject of an approval or authority under section 19;
(v) the goods are the subject of an approval under section 19A; and
(c) either:
(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: A person may commit an offence against subsection 20(2A) or (2C), or may contravene section 22AA (a civil penalty provision), by importing into Australia therapeutic goods that are exempt under section 18A.

Note 3: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

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(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

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(i) the goods are registered goods or listed goods in relation to the person;
(ii) the goods are exempt goods;
(iii) the goods are exempt under section 18A;
(iv) the goods are the subject of an approval or authority under section 19;
(v) the goods are the subject of an approval under section 19A.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Defence if person was not the sponsor of the goods

(5) It is a defence to a prosecution under subsection (1), (4) or (4A) if the defendant proves that the defendant was not the sponsor of the goods at the time of the importation, exportation, manufacture or supply, as the case may be.

Note: The defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

Exception

(6) Subsection (1) does not apply if:
(a) harm or injury did not, will not, or is not likely to, directly result from:
(i) the quality, safety or efficacy of the goods; or
(ii) a matter relating to the labelling or packaging of the goods; or
(iii) the improper use of the goods; or
(b) harm or injury would not, or would not be likely to, directly result from:
(i) the quality, safety or efficacy of the goods; or
(ii) a matter relating to the labelling or packaging of the goods; or
(iii) the improper use of the goods.

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Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

Application of Customs Act 1901

(7) Where:

(a) the importation or exportation of goods is an offence under subsection (1), (4) or (4A); and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act; as the case requires.

19C Notice required to adduce evidence in support of exception under subsection 19B(6)

(1) If:

(a) a defendant is committed for trial for an offence against subsection 19B(1); or

(b) an offence against subsection 19B(1) is to be heard and determined by a court of summary jurisdiction;

the committing magistrate or the court must:

(c) inform the defendant of the requirements of this section; and

(d) cause a copy of this section to be given to the defendant.

(2) A defendant must not, without leave of the court, adduce evidence in support of the exception under subsection 19B(6) unless:

(a) if paragraph (1)(a) applies—more than 21 days before the trial begins; or

(b) if paragraph (1)(b) applies—more than 21 days before the hearing of the offence begins;

he or she gives notice of particulars of the exception.

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(3) A defendant must not, without leave of the court, call any other person to give evidence in support of the exception unless:

(a) the notice under subsection (2) includes the name and address of the person or, if the name and address is not known to the defendant at the time he or she gives the notice, any information in his or her possession that might be of material assistance in finding the person; and

(b) if the name or the address is not included in the notice—the court is satisfied that the defendant before giving the notice took, and after giving the notice continued to take, all reasonable steps to ascertain the name or address; and

(c) if the name or address is not included in the notice, but the defendant subsequently ascertains the name or address or receives information that might be of material assistance in finding the person—the defendant immediately gives notice of the name, address or other information, as the case may be; and

(d) if the defendant is told by or on behalf of the prosecutor that the person has not been found by the name, or at the address, given by the defendant:

(i) the defendant immediately gives notice of any information in the defendant's possession that might be of material assistance in finding the person; or

(ii) if the defendant later receives any such information — the defendant immediately gives notice of the information.

(4) A notice purporting to be given under this section on behalf of the defendant by his or her legal practitioner is, unless the contrary is proved, taken as having been given with the authority of the defendant.

(5) Any evidence tendered to disprove that the exception applies may, subject to direction by the court, be given before or after evidence is given in support of the exception.

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(6) A notice of particulars of the exception must be given, in writing, to the Director of Public Prosecutions. A notice is taken as having been given if it is:

(a) delivered to or left at the Office of the Director of Public Prosecutions; or

(b) sent by certified mail addressed to the Director of Public Prosecutions at the Office of the Director of Public Prosecutions.

(7) In this section:

Director of Public Prosecutions means a person holding office as, or acting as, the Director of Public Prosecutions under the *Director of Public Prosecutions Act 1983*.

19D Civil penalties relating to registration or listing etc. of imported, exported, manufactured and supplied therapeutic goods

Civil penalty relating to importing, exporting, manufacturing or supplying goods for use in humans

(1) A person contravenes this subsection if:

(a) the person does any of the following:

(i) imports into Australia therapeutic goods for use in humans;

(ii) exports from Australia therapeutic goods for use in humans;

(iii) manufactures in Australia therapeutic goods for use in humans;

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

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(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Note: A person may commit an offence against subsection 20(2A) or (2C), or may contravene section 22AA (a civil penalty provision), by importing into Australia therapeutic goods that are exempt under section 18A.

Exception if person was not the sponsor of the goods

(2) Subsection (1) does not apply if the person proves that he or she was not the sponsor of the goods at the time of the importation, exportation, manufacture or supply, as the case may be.

Civil penalty relating to the importing of registered or listed goods

(3) A person contravenes this subsection if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person imports the goods into Australia; and

(ba) the person does not have the consent in writing of the Secretary; and

(c) the registration number or listing number of the goods is not set out on the label of the goods in the prescribed manner before the goods are supplied in Australia.

Maximum civil penalty:

(a) for an individual—200 penalty units; and

(b) for a body corporate—2,000 penalty units.

Civil penalty relating to the supply of registered or listed goods (4) A person contravenes this subsection if:

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(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person supplies the goods in Australia; and

(ba) the person does not have the consent in writing of the Secretary; and

(c) the registration number or listing number of the goods is not set out on the label of the goods in the prescribed manner.

Maximum civil penalty:

(a) for an individual—200 penalty units; and

(b) for a body corporate—2,000 penalty units.

Application of Customs Act 1901

(5) Where:

(a) the importation or exportation of goods contravenes subsection (1); and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act; as the case requires.

Decisions on whether to give consent

(6) The Secretary must, as soon as practicable after making a decision to give a consent mentioned in subsection (3) or (4), cause particulars of the decision to be published on the Department's website.

(7) The Secretary must, within 28 days after making a decision to refuse to give a consent mentioned in subsection (3) or (4), notify the applicant in writing of the decision and of the reasons for the decision.

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20 Criminal offences relating to notifying the Secretary and to importing goods exempt under section 18A

(1B) A person commits an offence if:

(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(1BA) A person commits an offence if:

(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

Penalty: 100 penalty units.

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(1BB) An offence against subsection (1BA) is an offence of strict liability.

(1C) For the purposes of paragraphs (1B)(c) and (1BA)(c):

(a) a manufacturer is ***properly notified*** to the Secretary if:

(i) the manufacturer was nominated, as a manufacturer of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the goods; and

(b) premises are ***properly notified*** to the Secretary if:

(i) the premises were nominated, as premises used in the manufacture of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the goods.

(2A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are exempt under section 18A; and

(c) the importation breaches a condition of the exemption.

Penalty: Imprisonment for 4 years or 240 penalty units, or both.

(2B) Strict liability applies to paragraph (2A)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(2C) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are exempt under section 18A; and

(c) the importation breaches a condition of the exemption.

Penalty: 60 penalty units.

(2D) An offence under subsection (2C) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

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20A Civil penalty relating to the importation, exportation, manufacture or supply of sponsored goods without proper notification

(1) A person contravenes this section if:

(a) the person does any of the following:

(i) imports therapeutic goods into Australia;

(ii) exports therapeutic goods from Australia;

(iii) manufactures therapeutic goods in Australia;

(iv) supplies therapeutic goods in Australia; and

(b) the person is the sponsor of the goods for use in humans; and

(c) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Meaning of ***properly notified***

(2) For the purposes of paragraph (1)(c):

(a) a manufacturer is ***properly notified*** to the Secretary if:

(i) the manufacturer was nominated, as a manufacturer of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the goods; and

(b) premises are ***properly notified*** to the Secretary if:

(i) the premises were nominated, as premises used in the manufacture of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the goods.

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21 Offence relating to wholesale supply

A person must not supply in Australia therapeutic goods for use in humans, being goods of which the person is not a sponsor, to another person who is not the ultimate consumer of the goods unless:

(a) the goods are registered goods or listed goods; or

(b) the goods are exempt goods; or

(ba) the goods are exempt under section 18A; or

(c) the goods are the subject of an approval or authority under section 19; or

(d) the goods are the subject of an approval under section 19A.

Penalty: 120 penalty units.

21A General criminal offences relating to this Part

Offences for making a false or misleading statement

(1) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

(c) the statement is false or misleading in a material particular; and

(d) either:

(i) the use of the medicine has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the medicine, if the medicine were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

(c) the statement is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Offences relating to breaching a condition of registration or listing of therapeutic goods

(5) A person commits an offence if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the registration or listing of the goods; and

(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(8) A person commits an offence if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the registration or listing of the goods.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(8A) A person commits an offence if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the registration or listing of the goods.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

Offences relating to the supply of therapeutic goods in breach of authority etc.

(9) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority; or

(ii) the supply is not in accordance with the conditions to which the authority is subject; or

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7); and

(d) either:

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(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:

(i) the supply is not in accordance with the authority; or

(ii) the supply is not in accordance with the conditions to which the authority is subject; or

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(9A) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 500 penalty units.

(10) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

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(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

(11A) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

(e) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(f) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:

(i) the supply is not in accordance with those rules; or

(ii) the supply is not in the circumstances specified in those rules; or

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

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(11C) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 500 penalty units.

(11D) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(11E) An offence against subsection (11D) is an offence of strict liability.

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Offences relating to using therapeutic goods without approval etc.

(12) A person commits an offence if:

(a) the person uses therapeutic goods; and

(b) the goods are used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) the goods are not:

(i) exempt goods; or

(ii) listed goods; or

(iii) registered goods; or

(iv) goods exempt under section 18A; or

(v) goods that are the subject of an approval under section 19A; and

(d) the goods are not used in accordance with:

(i) an approval or authority under section 19; or

(ii) a condition applicable under regulations made for the purposes of subsection 19(4A); and

(e) either:

(i) if the person used the goods in the treatment of another person—the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to that person; or

(ii) if the person used the goods solely for experimental purposes in humans—the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any of those persons.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(12A) A person commits an offence if:

(a) the person uses therapeutic goods; and

(b) the goods are used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) the goods are not:

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(i) exempt goods; or
(ii) listed goods; or
(iii) registered goods; or
(iv) goods exempt under section 18A; or
(v) goods that are the subject of an approval under section 19A; and
(d) the goods are not used in accordance with:
(i) an approval or authority under section 19; or
(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 500 penalty units.

(13) A person commits an offence if:
(a) the person uses therapeutic goods; and
(b) the goods are used:
(i) in the treatment of another person; or
(ii) solely for experimental purposes in humans; and
(c) the goods are not:
(i) exempt goods; or
(ii) listed goods; or
(iii) registered goods; or
(iv) goods exempt under section 18A; or
(v) goods that are the subject of an approval under section 19A; and
(d) the goods are not used in accordance with:
(i) an approval or authority under section 19; or
(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 100 penalty units.

(14) An offence against subsection (13) is an offence of strict liability.

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21B General civil penalties relating to this Part

Civil penalty for making a false or misleading statement

(1) A person contravenes this subsection if the person, in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2), makes a statement that is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Civil penalty relating to breaching a condition of registration or listing of therapeutic goods

(2) A person contravenes this subsection if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act that breaches a condition of the registration or listing of the goods.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Civil penalty for falsely representing therapeutic goods

(3) A person contravenes this subsection if:

(a) the person represents therapeutic goods that are not included in the Register as being so included; or

(b) the person represents therapeutic goods that are not exempt goods as being exempt goods; or

(c) the person represents therapeutic goods that are not goods exempt under section 18A as being goods exempt under that section; or

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(d) the person represents therapeutic goods that are included in one part of the Register as being included in another part of the Register; or

(e) the person represents therapeutic goods that are not the subject of an approval or authority under section 19 as being the subject of such an approval or authority; or

(f) the person represents therapeutic goods that are not the subject of an approval under section 19A as being the subject of such an approval.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Civil penalty for advertising therapeutic goods for an indication

(4) A person contravenes this subsection if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

22 General offences relating to this Part

(1) A person must not set out or cause to be set out, on a container or package that contains therapeutic goods or on a label of goods of that kind, a number that purports to be the registration number or listing number of the goods in relation to a particular person if the number is not that number.

Penalty: 60 penalty units.

(2) A person commits an offence if:

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(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion; and

(d) either:

(i) the use of the goods for the advertised indication has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods for the advertised indication, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Penalty: 100 penalty units.

(5A) An offence against subsection (5) is an offence of strict liability.

(6) A person commits an offence if:

(a) the person does an act or omits to do an act; and

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(b) the act or omission results in the breach of:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or

(ii) a condition of an approval or authority under section 19; or

(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or

(iv) a condition of an approval under section 19A; and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(7) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission results in the breach of:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or

(ii) a condition of an approval or authority under section 19; or

(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or

(iv) a condition of an approval under section 19A.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(7AA) A person commits an offence of strict liability if:

(a) the person does an act or omits to do an act; and

(b) the act or omission results in the breach of:

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(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or

(ii) a condition of an approval or authority under section 19; or

(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or

(iv) a condition of an approval under section 19A.

Penalty: 100 penalty units.

(7AB) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and

(b) the goods are exempt under section 18A; and

(c) the act or omission results in the breach of a condition of the exemption; and

(d) the act or omission is likely to cause a serious risk to public health.

Penalty: Imprisonment for 5 years or 2,000 penalty units, or both.

Note 1: A person may commit an offence against subsection 20(2A) or (2C), or contravene section 22AA (a civil penalty provision), by breaching a condition of an exemption of therapeutic goods under section 18A that relates to the importation of the goods.

Note 2: A person may commit an offence against subsection 30H(1) or (3) by breaching a condition of an exemption of therapeutic goods under section 18A that relates to records about the goods.

Note 3: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(7AC) Strict liability applies to paragraph (7AB)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(7AD) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and

(b) the goods are exempt under section 18A; and

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(c) the act or omission results in the breach of a condition of the exemption.

Penalty: Imprisonment for 4 years or 240 penalty units, or both.

(7AE) Strict liability applies to paragraph (7AD)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

22AA Civil penalty for breaching conditions

(1) A person contravenes this subsection if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and

(b) the goods are exempt under section 18A; and

(c) the act or omission breaches a condition of the exemption.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

(2) A person contravenes this subsection if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or

(ii) a condition of an approval or authority under section 19; or

(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or

(iv) a condition of an approval under section 19A.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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22A Criminal offences for false statements in applications for registration

(1) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with an application for registration of therapeutic goods; and

(c) the statement is false or misleading in a material particular; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with an application for registration of therapeutic goods; and

(c) the statement is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with an application for registration of therapeutic goods; and

(c) the statement is false or misleading in a material particular.

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Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

22B Civil penalty for false statements in applications for registration

A person contravenes this section if the person in or in connection with an application for registration of therapeutic goods, makes a statement that is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 1A—Provisional determinations for medicine

22C Applications for provisional determination

(1) A person may make an application to the Secretary for a provisional determination relating to a medicine of a kind prescribed by the regulations for the purposes of this subsection.

Note: If the Secretary makes the determination, the person applies under section 23 for registration of the medicine and that application passes preliminary assessment, then a different kind of evaluation of the medicine will occur under section 25.

(2) An application under subsection (1) must:

(a) be made in accordance with a form approved, in writing, by the Secretary; and

(b) be accompanied by the prescribed application fee; and

(c) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and

(d) satisfy any other requirement prescribed by the regulations for the purposes of this paragraph.

(3) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

22D Provisional determinations

(1) If a person makes an application, in accordance with subsection 22C(2), for a provisional determination relating to a medicine, the Secretary must decide to make, or to refuse to make, the determination.

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Criteria

(2) The Secretary may make the determination if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of this subsection are met in relation to the medicine. *Content of determination*

(3) The determination must specify:
(a) the person to whom the determination relates; and
(b) the medicine to which the determination relates; and
(c) the indication of the medicine to which the determination relates; and
(d) each active ingredient of the medicine to which the determination relates.

The determination may specify any other matters that the Secretary considers appropriate.

Notice of decision

(4) As soon as practicable after making the decision, the Secretary must:
(a) give the person written notice of the decision; and
(b) if the Secretary refuses to make the determination—set out the reasons for the refusal in the notice.

22E Period during which provisional determination is in force

(1) A provisional determination under section 22D relating to a medicine:
(a) comes into force on the day on which the Secretary gives the person notice under subsection 22D(4); and
(b) subject to this section and section 22F, remains in force for the initial period.

Note: For revocation of the determination, see section 22F.

(2) The ***initial period*** is 6 months or another period prescribed by the regulations for the purposes of this subsection.

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Extensions

(3) The person may make an application to the Secretary to extend the initial period.

(4) The application must:

(a) be in a form approved, in writing, by the Secretary; and

(b) be made at least 28 days before the determination would otherwise cease to be in force; and

(c) be accompanied by the prescribed application fee.

(5) On receiving the application, the Secretary must decide to extend, or to refuse to extend, the initial period.

(6) The Secretary may extend the initial period by 6 months, or another period prescribed by the regulations for the purposes of this subsection, if the Secretary:

(a) is still satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are met in relation to the medicine; and

(b) is satisfied that, if the Secretary were to make the extension, the person would make an application under section 23 for provisional registration of the medicine before the end of the extended period.

(7) As soon as practicable after making the decision, the Secretary must:

(a) give the person written notice of the decision; and

(b) if the Secretary refuses to extend the initial period—set out the reasons for the refusal in the notice.

(8) Only one extension may be given. *Effect of application under section 23*

(9) If the person to whom the provisional determination relates makes an application under section 23 for provisional registration of the medicine before the end of the initial period (or that period as extended), the determination remains in force until:

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(a) the person withdraws the application; or

(b) the application lapses in accordance with subsection 24(2); or

(c) the person gives the Secretary written notice under subsection 24E(2) that the person wishes to treat the application as having been refused; or

(d) the application is finally determined.

(10) For the purposes of paragraph (9)(d), an application is ***finally determined*** when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

22F Revocation of provisional determination

Revocation on Secretary's own initiative

(1) The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine.

Revocation on request

(2) The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine if the person requests the Secretary, in writing, to do so.

Notice of revocation

(3) As soon as practicable after making a revocation under this section, the Secretary must:

(a) give the person written notice of the revocation; and

(b) for a revocation under subsection (1)—set out the reasons for the revocation in the notice.

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Day revocation takes effect

(4) A revocation under this section takes effect on the day on which the Secretary gives the person notice of the revocation.

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Division 1B—Scientific advice about aspects of quality, safety or efficacy of medicine

22G Scientific advice about aspects of quality, safety or efficacy of medicine

Requests about aspects of the quality of medicine

(1) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the quality of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.

(2) Each request under subsection (1) must relate only to one aspect of the quality of the medicine.

Requests about aspects of the safety of medicine

(3) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the safety of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.

(4) Each request under subsection (3) must relate only to one aspect of the safety of the medicine.

Requests about aspects of the efficacy of medicine

(5) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the efficacy of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.

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(6) Each request under subsection (5) must relate only to one aspect of the efficacy of the medicine.

Secretary must give advice

(7) The Secretary must give advice in response to a request under this section that is made in accordance with this section.

How request is to be made

(8) A request under this section:

(a) must be made in accordance with a form approved, in writing, by the Secretary; and

(b) must be accompanied by the fee prescribed by the regulations; and

(c) may be accompanied by any information or documents the person making the request considers appropriate.

(9) An approval of a form may require or permit a request, information or a document to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

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Division 2—Registration and listing

23 Applications generally

A person may make an application to the Secretary for registration or listing of therapeutic goods.

23AA Applications for provisional registration of medicine

(1) If:

(a) a person makes an application under section 23 for the registration of a medicine; and

(b) a provisional determination under section 22D relating to the person, the medicine and the indication to which the application relates is in force when the application is made;

then, for the purposes of this Act, the application is taken to be an application for provisional registration of the medicine.

(2) If:

(a) in accordance with subsection 29(2), a medicine (the ***original medicine***) is provisionally registered because of an application by a person that, under subsection (1) of this section, is taken to be an application for provisional registration of the original medicine; and

(b) another medicine (the ***new medicine***) is taken, under subsection 16(1), to be separate and distinct from the original medicine; and

(c) the person makes an application under section 23 for the registration of the new medicine; and

(d) the person makes the application before the end of the provisional registration period for the original medicine under subsection 29(3) (including that period as extended under subsection 29(6)); and

(e) the person specifies in the application that the person is seeking provisional registration of the new medicine; and

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(f) at the time the person makes the application, the active ingredients of the new medicine are the same as the active ingredients of the original medicine; and

(g) at the time the person makes the application, the indications of the new medicine are the same as the indications of the original medicine;

then, for the purposes of this Act, the application is taken to be an application for provisional registration of the new medicine.

23A Classes of therapeutic goods

(1) The Secretary may, by notifiable instrument, specify different classes of therapeutic goods for the purposes of section 23B.

(2) Without limiting subsection (1), a class of therapeutic goods may be specified by reference to one or more of the matters referred to in paragraphs 16(1)(a) to (g) or 16(1A)(a) to (d).

23B Requirements relating to applications for registration of therapeutic goods and listing of medicines under section 26AE

(1) If an application is made under section 23 for:

(a) registration of therapeutic goods (including an application for provisional registration of a medicine); or

(b) the listing of a medicine under section 26AE;

the Secretary must carry out an assessment of whether the requirements set out in subsection (2) have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that class of therapeutic goods; or

(ii) in such other manner as is approved, in writing, by the Secretary for that class of therapeutic goods;

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(b) the prescribed application fee for that class of therapeutic goods must be paid;
(c) the application must be delivered to an office of the Department specified by the Secretary;
(d) the application must be accompanied by information that is:
(i) of a kind determined under subsection (9) for that class of therapeutic goods; and
(ii) in a form determined under subsection (10) for that class of therapeutic goods;
(e) if the application is for the registration of restricted medicine—the application must be accompanied by product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;
(f) if the Secretary so requires—the applicant must:
(i) deliver to the Department a reasonable number of samples of the goods; and
(ii) do so in a manner approved, in writing, by the Secretary;
(g) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application must be accompanied by a statement from the applicant certifying that:
(i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
(ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
(iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
(h) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application must be accompanied by a statement from the applicant certifying that:

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(i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and

(ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those conditions.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

(4) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(5) Subsection (4) does not apply if the period within which the Secretary must, under section 25, evaluate the goods to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and different manners for making applications for different classes of therapeutic goods that are specified under section 23A.

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(8) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to a class of therapeutic goods that is specified under section 23A.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of therapeutic goods that is specified under section 23A.

23C Requirements relating to applications for listing of therapeutic goods under section 26 or 26A

(1) This section applies if an application is made under section 23 for listing of therapeutic goods under section 26 or 26A.

(2) The application complies with this section if:

(a) the application is made in accordance with a form approved, in writing, by the Secretary or in such other manner as is approved, in writing, by the Secretary for the purposes of this paragraph; and

(b) the application is delivered to an office of the Department specified by the Secretary; and

(c) the prescribed application fee has been paid; and

(d) the applicant has delivered to the office to which the application was made such information, in a form approved, in writing, by the Secretary, as will allow the determination of the application; and

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(e) if the Secretary so requires—the applicant has delivered to the office to which the application was made a reasonable number of samples of the goods; and

(f) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application is accompanied by a statement from the applicant certifying that:

(i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and

(ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and

(g) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application is accompanied by a statement from the applicant certifying that:

(i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and

(ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those conditions.

Note: To be listed, an application must comply with this section: see sections 26, 26A and 26AB.

(3) The Secretary may, by legislative instrument, determine forms of information for the purposes of the application of paragraph (2)(d).

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(4) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:
(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

24 Applications for registration

(1) This section applies if:
(a) an application is made for the registration of therapeutic goods under section 23; and
(b) the goods are goods that are required to be registered; and
(c) the application has passed preliminary assessment.

(1A) A fee specified in, or determined in accordance with, the regulations is payable by the applicant in respect of the evaluation of the goods for registration, and the Secretary must notify each such applicant of the amount of the evaluation fee.

(2) An application for registration of therapeutic goods lapses if:
(a) any part of the evaluation fee payable in respect of those goods remains unpaid at the end of the period of 2 months after the day on which the amount became due and payable; or
(b) the application contains information that is inaccurate or misleading in a material particular; or
(c) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 31, is inaccurate or misleading in a material particular; or
(d) the applicant fails to comply with a requirement under section 31 to give information consisting of individual patient data in relation to the goods.

(3) In this section, ***individual patient data***, in relation to therapeutic goods, means information, derived from clinical trials, relating to individuals before, during and after the administration of the goods

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to those individuals, including, but not limited to, demographic, biochemical and haematological information.

24A When evaluation fee due for payment

Subject to section 24B, an evaluation fee under section 24 payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

24B Payment of evaluation fee by instalments

(1) The regulations may provide for the payment of an evaluation fee under section 24 to be made by such instalments and at such times as are ascertained in accordance with the regulations, and the evaluation fee is due and payable accordingly.

(2) Regulations made for the purposes of subsection (1) may provide that a person is not allowed to pay an evaluation fee under section 24 by instalments if any part of an instalment of:

(a) that or any other evaluation fee under section 24 payable by the person; or

(b) any assessment fee under section 41LA payable by the person;

was unpaid immediately after the time when it became due for payment.

(3) Subsection (2) does not limit the generality of subsection (1).

24C Recovery of evaluation fee

An evaluation fee under section 24 may be recovered by the Commonwealth as a debt due to the Commonwealth.

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24D Refund of evaluation fee where evaluation not completed within prescribed period

(1) This section applies to an application under section 23 in relation to therapeutic goods for the evaluation of which a period is prescribed under paragraph 63(2)(da).

(2) If:

(a) the applicant has paid the whole of the evaluation fee; and

(b) the evaluation is completed, but not within the period referred to in subsection (1);

then 25% of the evaluation fee must be refunded to the applicant.

(3) For the purposes of subsection (2), the evaluation is taken to be completed when the applicant is notified of the Secretary's decision under subsection 25(3) in relation to the goods.

24E Deemed refusal of application

(1) This section applies in the case of an application under section 23 in relation to therapeutic goods for the evaluation of which a period is prescribed under paragraph 63(2)(da).

(2) If, at the end of the period referred to in subsection (1), the evaluation has not been completed, the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

(4) Where a notice has been given, this Act (except for subsection 60(5)) has effect as if:

(a) the Secretary had decided not to register the goods the subject of the application; and

(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

(c) the Minister's decision had been made on the day on which notice was given to the Secretary under subsection (2).

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25 Evaluation of therapeutic goods

(1) If:

(a) an application is made for the registration of therapeutic goods in relation to a person under section 23; and

(b) the application has passed preliminary assessment;

the Secretary must evaluate the goods for registration having regard to:

(c) unless the application is one referred to in paragraph (d) — whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established; and

(d) for an application for provisional registration of a medicine:

(i) whether, based on preliminary clinical data, the safety and efficacy of the medicine for the purposes for which it is to be used have been satisfactorily established; and

(ii) whether the quality of the medicine for the purposes for which it is to be used has been satisfactorily established; and

(iii) if subsection 23AA(1) applies in relation to the application—whether, if the Secretary were to register the medicine, the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that registration would commence; and

(da) if:

(i) the applicant is applying for the registration of restricted medicine; or

(ii) the applicant is applying for the registration of medicine (other than restricted medicine) and the applicant has been given a notice in writing by the Secretary requiring the applicant to give to the Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;

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the product information given by the applicant in relation to the medicine; and

(e) whether the presentation of the goods is acceptable; and

(f) whether the goods conform to any standard applicable to the goods; and

(fa) whether:

(i) the applicable provisions of the Therapeutic Goods Advertising Code; and

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or 5-1A or the regulations;

are complied with in relation to the goods; and

(g) if a step in the manufacture of the goods has been carried out outside Australia—whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and

(h) if the goods have been manufactured in Australia—whether the goods have been manufactured in accordance with Part 3-3; and

(i) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether, if the Secretary were to register the goods, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the goods would contravene those prohibitions; and

(ia) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— whether, if the Secretary were to register the goods, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the goods would contravene those conditions; and

(j) whether the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(ja) whether all of the manufacturers of the goods are nominated as manufacturers of the goods in the application; and

(k) such other matters (if any) as the Secretary considers relevant.

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Note: The Secretary must not use protected information when evaluating therapeutic goods for registration: see section 25A.

(2) In making a decision for the purposes of paragraph (1)(g), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(2AA) If:

(a) the applicant is applying for the registration of a medicine; and

(b) the Secretary has given the applicant or any other person advice under section 22G in relation to the medicine;

the Secretary must have regard to the advice in evaluating the medicine under this section.

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(2AB) Subsection (2AA) does not limit the matters the Secretary may take into account in evaluating the medicine under this section.

(2A) An evaluation under this section of goods in relation to which a period has been prescribed under paragraph 63(2)(da) must be completed within that period.

(2B) If therapeutic goods are exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

(2C) If a person is exempt from the operation of Part 3-3 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 3-3 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(2D) If:

(a) therapeutic goods were made outside Australia; and

(b) had the goods been made in Australia, they would have been exempt from the operation of Part 3-3;

subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.

(2E) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to:

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(2F) For the purposes of subsection (2E), a Convention country is a country that is a party to the Mutual Recognition Convention.

(2G) Information referred to in subsection (2E) and provided in accordance with the Mutual Recognition Convention is to be

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treated as equivalent to information obtained as a result of an inspection under Part 3-3 of this Act.

(3) After an evaluation under this section of goods has been completed, the Secretary must decide:

(a) to register the goods; or

(b) not to register the goods.

Note: See also sections 25AA (approved product information for medicine), 25AB (registration of therapeutic goods) and 25AC (notice of decision not to register therapeutic goods).

25AAA Therapeutic goods (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make therapeutic goods (priority applicant) determinations.

(2) A ***therapeutic goods (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 23 application that may be made by the person for the registration of therapeutic goods specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for therapeutic goods (priority applicant) determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application;

(e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

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(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a therapeutic goods (priority applicant) determination;

(b) the consequences of the revocation of a therapeutic goods (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) A period prescribed under paragraph 63(2)(da) for the evaluation of therapeutic goods covered by a section 23 application for which the applicant is a priority applicant may be shorter than the period prescribed under that paragraph for the evaluation of therapeutic goods covered by a section 23 application for which the applicant is not a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 23 application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(9) If a therapeutic goods (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A therapeutic goods (priority applicant) determination made under the regulations is not a legislative instrument.

(11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of a person in a therapeutic goods (priority applicant) determination.

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Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with specification by class.

25AA Approved product information for medicine

(1) The Secretary must approve product information in relation to therapeutic goods if:

(a) the Secretary decides, under subsection 25(3), to register the goods; and

(b) the goods are:

(i) restricted medicine; or

(ii) medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph 25(1)(da)(ii).

Note: Subsection (4) deals with variation of the product information.

(1A) However, the Secretary must not approve product information in relation to therapeutic goods under subsection (1) unless the Secretary is satisfied that the product information reflects the basis on which the Secretary decided under subsection 25(3) to register the goods.

(1B) If:

(a) there is medicine included in the Register in relation to a person and there is no product information approved under this section in relation to the medicine; and

(b) the medicine becomes restricted medicine;

the Secretary may, by written notice given to the person, require the person to:

(c) give the Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine; and

(d) give the Secretary that product information within the period specified in the notice (which must be at least 30 days after the notice is given).

(1C) If the person complies with subsection (1B), the Secretary must approve product information in relation to the medicine that

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reflects the basis on which the medicine is registered at the time of the approval. The Secretary must, by written notice given to the person, set out the product information so approved.

Note: Subsection (4) deals with variation of the product information.

Transitional

(2) If:

(a) at the start of the day the first instrument made under subsection 3(2A) or (2B) takes effect, there is medicine included in the Register in relation to a person; and

(b) before that day, the Secretary, in a notice given under subsection 25(4) (as in force on that day) to the person in relation to the registration of the medicine, specified the product information that was approved by the Secretary in relation to the medicine;

then that product information (including as varied before that day) is, on and after that day, the product information that is approved under this section in relation to the medicine.

Note: Subsection (4) deals with variation of the product information.

(3) If:

(a) before the day the first instrument made under subsection 3(2A) or (2B) takes effect, a person made an application to include medicine in the Register; and

(b) before that day and in relation to that application, the Secretary, in a notice given under subsection 25(4) (as in force on that day) to the person, specified the product information that was approved by the Secretary in relation to the medicine; and

(c) on or after that day and in relation to that application, the Secretary includes the medicine in the Register in relation to the person;

then that product information (including as varied before that inclusion) is, on and after the day the registration of the medicine commences, the product information that is approved under this section in relation to the medicine.

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Note: Subsection (4) deals with variation of the product information.

Variations

(4) If:

(a) there is medicine included in the Register in relation to a person and there is product information approved under this section in relation to the medicine; and

(b) either:

(i) under section 9D, the Secretary varies the entry in the Register in relation to the medicine; or

(ii) there is a change in the conditions to which the inclusion of the medicine is subject; and

(c) as a result of that variation or change, the Secretary is satisfied that a variation to that product information is required;

the Secretary may, by notice in writing given to the person, make any variations that the Secretary considers appropriate to the product information that is approved in relation to the medicine.

(4A) Without limiting subsection (4), a variation to the product information is not appropriate unless:

(a) if subparagraph (4)(b)(i) applies—the product information, as varied, reflects the basis on which the Secretary decided under section 9D to vary the entry in the Register in relation to the medicine; or

(b) if subparagraph (4)(b)(ii) applies—the product information, as varied, reflects the basis on which the Secretary decided under section 28 to change the conditions to which the inclusion of the medicine is subject.

(5) To avoid doubt, if product information that is approved in relation to medicine is varied under this section, that product information, as varied, becomes the product information that is approved under this section in relation to the medicine.

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25AB Registration of therapeutic goods etc.

(2) If:

(a) an application is made under section 23 for the registration of therapeutic goods in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides under subsection 25(3) to register the goods;

the Secretary must, in accordance with subsection (3), notify the applicant in writing of the decision within 28 days of making the decision.

(3) The notice must:

(a) set out the decision under subsection 25(3) to register the goods; and

(b) if the goods are restricted medicine or medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph 25(1)(da)(ii)—set out the product information approved under subsection 25AA(1) for the medicine; and

(c) inform the applicant that the goods will not be included in the Register unless and until the applicant gives the Secretary:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application.

(4) If the applicant gives the Secretary the certificate referred to in subparagraph (3)(c)(i) or the notice referred to in subparagraph (3)(c)(ii), the Secretary must:

(a) include the goods in the Register; and

(b) give the applicant a certificate of registration.

(5) To avoid doubt, if the applicant gives the Secretary the certificate referred to in subparagraph (3)(c)(i) or the notice referred to in subparagraph (3)(c)(ii), the Secretary must include the goods in the

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Register under paragraph (4)(a) without inquiring into the correctness of the certificate or the notice.

Date registration commences

(6) The registration of therapeutic goods commences on the day specified in the certificate of registration.

25AC Notice of decision not to register therapeutic goods

If:

(a) an application is made under section 23 for the registration of therapeutic goods in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides under subsection 25(3) not to register the goods;

the Secretary must notify the applicant in writing of the decision, and the reasons for the decision, within 28 days of making the decision.

25A When the Secretary must not use protected information

(1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.

(2) Information is ***protected information*** if:

(a) the information was given to the Secretary in relation to an application to register therapeutic goods (the ***new goods***) consisting of, or containing, an active component; and

(b) the information is about the active component and is not available to the public; and

(c) when the application to register the new goods was lodged:

(i) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and

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(ii) no such therapeutic goods had been included in the Register at any time before then; and

(d) the new goods became registered on or after the commencement of this subsection; and

(e) 5 years have not passed since the day the new goods became registered; and

(f) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.

(3) For the purposes of subsection (2), an ***active component***, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

26 Listing of therapeutic goods

(1) Where:

(a) an application is made for the listing of therapeutic goods in relation to a person under section 23; and

(aaa) the application complies with section 23C; and

(aa) the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application; and

(b) the person has complied with any requirements made by the Secretary under section 31 in relation to the goods; and

(ba) the goods are not goods which may be listed under section 26A or 26AE;

then, subject to this section, the Secretary is not to refuse to list the goods in relation to the person except where the Secretary is satisfied that:

(c) the goods are not eligible for listing; or

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(d) the goods are not safe for the purposes for which they are to be used; or

(e) the presentation of the goods is unacceptable; or

(f) the goods do not conform to a standard applicable to the goods; or

(fa) either of the following has not been complied with in relation to the goods:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or the regulations; or

(g) if a step in the manufacture of the goods has been carried out outside Australia—the manufacturing and quality control procedures used in the manufacture of the goods are not acceptable; or

(h) if the goods have been manufactured in Australia—the goods have been manufactured contrary to Part 3-3; or

(j) if the goods have been manufactured in Australia, or imported into Australia, solely for export—a relevant authority of the country to which the goods are to be exported has not confirmed its willingness to accept the goods and:

(i) the goods have been refused registration or listing for supply in Australia; or

(ii) the Secretary requires such a confirmation for a reason other than because the goods have been refused registration or listing; or

(k) the goods do not comply with prescribed quality or safety criteria; or

(l) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those prohibitions; or

(la) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— imports into Australia, exports from Australia or supplies in

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Australia of the goods would contravene one or more of those conditions; or

(m) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(n) one or more of the manufacturers of the goods are not nominated as manufacturers of the goods in the application.

(1AA) If:

(a) a medicine (the ***original medicine***) is included in the Register in relation to a person; and

(b) the person makes an application under section 23 for the listing of a medicine (the ***new medicine***) under this section; and

(ba) the application complies with section 23C; and

(c) the Secretary is satisfied that paragraphs (1)(a) to (ba) are satisfied in relation to the application; and

(d) the Secretary is satisfied that the new medicine has the same characteristics as the original medicine apart from the characteristics specified in an instrument under subsection (1AB);

the Secretary may list the new medicine in relation to the person.

(1AB) The Minister may, by legislative instrument, specify characteristics for the purposes of paragraph (1AA)(d).

(1A) To avoid doubt, if:

(a) an application is made for the listing of therapeutic goods in relation to a person under section 23; and

(aa) the application complies with section 23C; and

(b) the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

(ii) a notice that a certificate under that subsection is not required in relation to the application; and

(c) the other requirements in subsection (1) are met;

the Secretary must list the goods under subsection (1) without inquiring into the correctness of the certificate or the notice.

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(2) In making a decision for the purposes of paragraph (1)(g), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(2A) If therapeutic goods are exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

(2B) If a person is exempt from the operation of Part 3-3 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 3-3 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(2C) If:

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(a) therapeutic goods were made outside Australia; and

(b) had the goods been made in Australia, they would have been exempt from the operation of Part 3-3;

subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.

(2D) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to:

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(2E) For the purposes of subsection (2D), a Convention country is a country that is a party to the Mutual Recognition Convention.

(2F) Information referred to in subsection (2D) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 3-3 of this Act.

(3) Where an application is made, the Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, in the case of a decision not to list the goods, of the reasons for the decision.

(4) As soon as practicable after an applicant has been informed that therapeutic goods in respect of which an application was made are acceptable for listing, the Secretary must give to the applicant a certificate of listing of the goods, and the listing of the goods commences on the day specified for the purpose in the certificate.

26A Listing of certain medicines

(1) If:

(a) an application is made for the listing of medicine in relation to a person under section 23; and

(aa) the application complies with section 23C; and

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(b) the application is accompanied by either:
(i) the certificate required under subsection 26B(1); or
(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application; and
(c) the requirements of subsection (2) and (where applicable) subsections (2A), (3) and (4A) have been complied with; and
(d) the medicine is not export only medicine; and
(e) the medicine is not one that has previously had its registration or listing cancelled;

the Secretary must list the medicine in relation to the person.

(1A) To avoid doubt, if:
(a) an application is made for the listing of a medicine in relation to a person in accordance with section 23; and
(aa) the application complies with section 23C; and
(b) the application is accompanied by either:
(i) the certificate required under subsection 26B(1); or
(ii) a notice that a certificate under that subsection is not required in relation to the application; and
(c) the other requirements in subsection (1) are met;

the Secretary must list the medicine under subsection (1) without inquiring into the correctness of the certificate or the notice.

(2) The applicant must certify that:
(a) the medicine is eligible for listing; and
(b) the medicine is safe for the purposes for which it is to be used; and
(c) the presentation of the medicine is not unacceptable; and
(ca) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and
(cb) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and

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(d) the medicine conforms to every standard (if any) applicable to the medicine; and

(da) both of the following are complied with in relation to the medicine:

(i) the applicable provisions of the Therapeutic Goods Advertising Code;

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and

(e) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and

(f) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and

(fa) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and

(fb) the medicine's label:

(i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and

(ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and

(fba) if the medicine's label contains one or more indications— each indication:

(i) is covered by a determination under paragraph 26BF(1)(a); and

(ii) is proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(fc) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and

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(fd) each indication proposed to be accepted in relation to the inclusion of the medicine in the Register is covered by a determination under paragraph 26BF(1)(a); and

(fe) if a determination under paragraph 26BF(1)(b) specifies requirements in relation to an indication proposed to be accepted in relation to the inclusion of the medicine in the Register—none of the requirements have been contravened; and

(g) the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(h) all the manufacturers of the medicine are nominated as manufacturers in the application; and

(i) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and

(j) both:

(i) the applicant holds information or evidence to support any claim (other than a claim that is an indication) proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

(ja) both:

(i) the applicant holds information or evidence to support each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

(k) the information included in or with the application is correct.

(2A) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

(2B) The Minister may, by legislative instrument, specify requirements for the purposes of subparagraph (2)(j)(ii) or (2)(ja)(ii).

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(3) Subject to subsection (7), if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

(4) In deciding whether so to certify for the purposes of subsection (3), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the medicine has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the medicine; or

(ia) if a step in the manufacture of the medicine has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the medicine; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the medicine is of an acceptable standard; and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the medicine to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection; and

(c) whether the applicant has complied with any requirements made by the Secretary under section 31 in relation to the manufacture or preparation of the medicine.

(4A) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

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(5) If a medicine is exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the medicine, subsection (2) has effect, in relation to the medicine, as if paragraph (2)(e) were omitted.

(6) If a person (the ***manufacturer***) is exempt from the operation of Part 3-3 in relation to a step in the manufacture of a medicine, subsection (2) has effect, in relation to the medicine, as if the reference in paragraph (2)(e) to a person who is the holder of a licence were a reference to the manufacturer to the extent that Part 3-3 applies to the manufacturer in relation to the manufacture of the medicine.

(7) If:

(a) a medicine was made outside Australia; and

(b) had the medicine been made in Australia, it would have been exempt from the operation of Part 3-3;

subsection (3) does not apply in relation to the medicine.

(9) As soon as practicable after a medicine has been listed under this section, the Secretary must give to the applicant a certificate of listing of the medicine. The listing of the medicine commences on the day specified for the purpose in the certificate.

26AB Application for listing of certain medicines following efficacy evaluation

(1) If:

(a) an application is made under section 23 for the listing of medicine in relation to a person; and

(b) the application passes preliminary assessment; and

(c) the requirements of subsections (2), (3), (4) and (6) have been complied with; and

(d) the medicine is not a medicine which may be listed under section 26A; and

(e) the medicine is not export only medicine; and

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(f) the medicine is not one that has previously had its registration or listing cancelled;

the Secretary must evaluate the medicine for listing under section 26AE.

(2) The applicant must certify that:

(a) the medicine is eligible for listing; and

(b) the medicine is safe for the purposes for which it is to be used; and

(c) the presentation of the medicine is not unacceptable; and

(d) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and

(e) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and

(f) the medicine conforms to every standard (if any) applicable to the medicine; and

(g) both of the following are complied with in relation to the medicine:

(i) the applicable provisions of the Therapeutic Goods Advertising Code;

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and

(h) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and

(i) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and

(j) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and

(k) the medicine's label:

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(i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and

(ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and

(l) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and

(m) the applicant has available sufficient information to substantiate each claim and each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(n) the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(o) all the manufacturers of the medicine are nominated as manufacturers in the application; and

(p) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and

(q) the information included in or with the application is complete and correct.

(3) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

(4) Subject to subsection (9), if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

(5) In deciding whether to certify for the purposes of subsection (4), the matters that may be taken into account include:

(a) whether the applicant has provided:

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(i) if a step in the manufacture of the medicine has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the medicine; or

(ii) if a step in the manufacture of the medicine has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the medicine; or

(iii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the medicine is of an acceptable standard; and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the medicine to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection; and

(c) whether the applicant has complied with any requirements made by the Secretary under section 31 in relation to the manufacture or preparation of the medicine.

(6) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

(7) If a medicine is exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the medicine, subsection (2) has effect, in relation to the medicine, as if paragraph (2)(h) were omitted.

(8) If a person (the ***manufacturer***) is exempt from the operation of Part 3-3 in relation to a step in the manufacture of a medicine, subsection (2) has effect, in relation to the medicine, as if the reference in paragraph (2)(h) to a person who is the holder of a

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licence were a reference to the manufacturer to the extent that Part 3-3 applies to the manufacturer in relation to the manufacture of the medicine.

(9) If:

(a) a medicine was made outside Australia; and

(b) had the medicine been made in Australia, it would have been exempt from the operation of Part 3-3;

subsection (4) does not apply in relation to the medicine.

26AC Evaluation fees for listing of medicine under section 26AE

(1) This section applies if:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the application has passed preliminary assessment.

(2) A fee (the ***evaluation fee***) specified in or determined in accordance with the regulations is payable by the applicant in respect of the evaluation of a medicine for listing under section 26AE.

(3) The Secretary must notify each applicant of the amount of the evaluation fee.

(4) The evaluation fee payable by an applicant:

(a) is due and payable on the day on which the applicant is notified of the amount of the evaluation fee; and

(b) may be recovered by the Commonwealth as a debt due to the Commonwealth.

(5) If:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the applicant has paid the whole of the evaluation fee; and

(c) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

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(d) the evaluation is completed, but not within that period;

then 25% of the evaluation fee must be refunded to the applicant.

(6) For the purposes of paragraph (5)(d), the evaluation is taken to be completed when the applicant is notified of the Secretary's decision under subsection 26AE(3) in relation to the medicine.

26AD Lapsing and deemed refusal of applications for listing of medicine under section 26AE

Lapsing of applications

(1) An application for the listing of a medicine under section 26AE lapses if:

(a) any part of the evaluation fee referred to in section 26AC remains unpaid at the end of 28 days after the day on which the amount became due and payable; or

(b) the application contains information that is inaccurate or misleading in a material particular; or

(c) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

Deemed refusal of applications

(2) If:

(a) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

(b) at the end of that period, the evaluation has not been completed;

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

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(4) If a notice has been given, this Act (except subsection 60(5)) has effect as if:
(a) the Secretary had decided not to list the medicine which is the subject of the application; and
(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and
(c) the Minister's decision had been made on the day on which notice was given to the Secretary under subsection (2).

26AE Evaluation and listing of certain medicines

Evaluation

(1) If:
(a) an application is made under section 23 for the listing of a medicine in relation to a person under this section; and
(b) the application has passed preliminary assessment;
the Secretary must evaluate the medicine having regard to:
(c) whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established; and
(d) such other matters (if any) as the Secretary considers relevant.

Note: The Secretary must not use restricted information when evaluating the medicine for listing: see section 26AF.

(2) If a period in relation to which an evaluation under this section must be completed has been prescribed under paragraph 63(2)(daaaa), the evaluation must be completed within that period.

Secretary must decide whether to list medicine

(3) After an evaluation under this section of goods has been completed, the Secretary must decide:
(a) to list the medicine; or
(b) not to list the medicine.

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Decision to list

(4) If the Secretary decides under subsection (3) to list the medicine, the Secretary must, in accordance with subsection (5), notify the applicant in writing of the decision within 28 days of making the decision.

(5) The notice must:

(a) set out the decision under subsection (3) to list the medicine in relation to the person; and

(b) inform the applicant that the medicine will not be included in the Register unless and until the applicant gives the Secretary:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application.

(6) If the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in subparagraph (5)(b)(ii), the Secretary must:

(a) include the medicine in the Register; and

(b) give the applicant a certificate of listing.

(7) To avoid doubt, if the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in subparagraph (5)(b)(ii), the Secretary must include the medicine in the Register under paragraph (3)(a) without inquiring into the correctness of the certificate or the notice.

Date listing commences

(8) The listing of the medicine commences on the day specified for the purpose in the certificate.

Refusal to list medicine

(9) If:

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(a) an application is made for the listing of medicine in relation to a person; and

(b) the Secretary decides under subsection (3) not to list the medicine;

the Secretary must notify the applicant in writing of the decision, and the reasons for the decision, within 28 days of making the decision.

26AF When the Secretary must not use restricted information in evaluating medicine for listing under section 26AE

(1) If an application is made under section 23 for the listing of a medicine under section 26AE, then, in evaluating the medicine under section 26AE, the Secretary must not use information about other medicine that is restricted information.

(2) Information is ***restricted information*** if:

(a) the information was given to the Secretary in relation to an application made under section 23 for the listing of a medicine (the ***existing medicine***) under section 26AE; and

(b) the information is derived from a clinical trial in relation to an indication of the existing medicine, where:

(i) the trial number of that trial is specified in the application for the listing of the existing medicine; and

(ii) the Secretary is satisfied that the trial number of that trial is set out in a registry prescribed by the regulations for the purposes of this subparagraph; and

(c) that indication is either:

(i) a use of the existing medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or

(ii) a use of the existing medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or

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injury that, under the Therapeutic Goods Advertising Code, is a serious form; and

(d) at the time (the ***relevant time***) the application for the listing of the existing medicine was made:

(i) that indication was not covered by a determination under paragraph 26BF(1)(a); and

(ii) no other medicine with that indication, and with the same active ingredients as the existing medicine, was included in the Register under section 26AE; and

(da) no other medicine with that indication, and with the same active ingredients as the existing medicine, had been included in the Register under section 26AE at any time before the relevant time; and

(e) the existing medicine was listed under section 26AE on or after the commencement of this subsection; and

(ea) the Secretary relied on the information in deciding to list the existing medicine; and

(eb) at all times during the period:

(i) beginning on the day the application for the listing of the existing medicine was made; and

(ii) ending at the end of the day before the day that the existing medicine was included in the Register;

the information (except information set out in a registry prescribed for the purposes of subparagraph (b)(ii)) was not available to the public; and

(f) 5 years have not passed since the day that listing commenced; and

(g) the person in relation to whom the existing medicine is listed has not given the Secretary permission in writing for the Secretary to use the information.

(3) A registry prescribed for the purposes of subparagraph (2)(b)(ii):

(a) may be a registry established within or outside Australia; and

(b) must be a registry that is accessible by the public.

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26B Certificates required in relation to patents

(1A) A certificate is required under subsection (1) in relation to an application for registration or listing of therapeutic goods only if:

(a) the applicant is required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing; and

(b) in order to satisfy that requirement, the applicant relies (in whole or in part) on evidence or information that another person submitted to the Secretary:

(i) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and

(ii) as part of the process of applying for the registration or listing of those other goods.

(1) The certificate required under this subsection is either:

(a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

(2) A person commits an offence if:

(a) the person gives a certificate required under subsection (1); and

(b) the certificate is false or misleading in a material particular.

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Penalty: 1,000 penalty units.

(3) For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent.

(4) In this section:

patent has the same meaning as in the *Patents Act 1990*.

26BA Approved form for notices

An approval of a form for a notice for the purposes of subsection 25AB(3), 26(1), 26A(1) or 26AE(5) may require or permit the notice to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

26BB Permissible ingredients

(1) The Minister may, by legislative instrument, make a determination specifying either or both of the following:

(a) ingredients;

(b) for some or all of those ingredients—requirements in relation to those ingredients being contained in medicine.

Note: A person seeking the listing of a medicine under section 26A or 26AB must certify that:
(a) the medicine does not contain an ingredient that is not specified in the determination; and
(b) none of the requirements specified in the determination in relation to ingredients being contained in the medicine have been contravened.

Requirements

(2) The requirements referred to in paragraph (1)(b) may relate to particular ingredients not being contained in particular medicine.

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(2A) The requirements referred to in paragraph (1)(b) may relate to a particular ingredient being contained in particular medicine only in the circumstances specified in the determination in relation to the ingredient.

(3) The requirements referred to in paragraph (1)(b) may relate to permitted concentrations or permitted total amounts of ingredients.

(4) Subsections (2), (2A) and (3) do not limit paragraph (1)(b).

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicine.

Limitations on determination under subsection (1)

(6) The Minister may, by legislative instrument, make a determination specifying either or both of the following:

(a) ingredients that must not be specified under paragraph (1)(a);

(b) requirements that must not be specified under paragraph (1)(b) in relation to ingredients being contained in medicine.

(7) A determination under paragraph (6)(b) may make different provision for different classes of medicine.

Incorporation of instruments

(8) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under this section may make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

26BC Variation of determination under section 26BB—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BB.

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26BD Requirements relating to an application for variation of a section 26BB determination

(1) A person may make an application to the Secretary for a recommendation by the Secretary that the Minister vary a section 26BB determination.

(2) If such an application is made, the Secretary must carry out an assessment of whether the requirements set out in subsection (3) have been met in relation to the application.

(3) The requirements are as follows:

(a) the application must be made in accordance with a form approved, in writing, by the Secretary;

(b) the application must set out the recommendation sought;

(c) the prescribed application fee must be paid;

(d) the application must be delivered to an office of the Department specified in the form;

(e) the application must be accompanied by information that is:

(i) of a kind determined under subsection (8); and

(ii) in a form determined under subsection (9).

Passing preliminary assessment

(4) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (2), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (3) have been met in relation to the application.

(5) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

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Approval of forms etc.

(7) An approval of a form mentioned in paragraph (3)(a) may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(8) The Secretary may, by legislative instrument, determine a kind of information for the purposes of subparagraph (3)(e)(i).

(9) The Secretary may, by legislative instrument, determine a form of information for the purposes of subparagraph (3)(e)(ii).

26BDA Lapsing of application for variation of a section 26BB determination

If an application made under subsection 26BD(1) has passed preliminary assessment, the application lapses if:

(a) the application contains information that is inaccurate or misleading in a material particular; or

(b) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular; or

(c) the evaluation fee prescribed for the purposes of paragraph 26BE(3)(b) has not been paid before the end of the period worked out in accordance with the regulations.

26BE Evaluation of whether to make recommendation for variation of a section 26BB determination

Decision by Secretary whether to make recommendation (3) If:

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(a) an application is made under subsection 26BD(1) for a recommendation by the Secretary that the Minister vary a section 26BB determination; and

(aa) the application has passed preliminary assessment; and

(b) any applicable prescribed evaluation fee has been paid; and

(c) if further information is required to be given under subsection (3A) within a specified period—the information is given within that period;

the Secretary must carry out an evaluation of whether to make the recommendation.

(3A) The Secretary may, by written notice given to a person who has made an application under subsection 26BD(1), require the person to:

(a) give the Secretary such further information in connection with the application as is specified in the notice; and

(b) do so within such reasonable period as is specified in the notice.

(4) After carrying out the evaluation, the Secretary must:

(a) make the recommendation; or

(b) refuse to make the recommendation.

(5) In deciding whether to make the recommendation, the Secretary must have regard to:

(a) the quality and safety of the ingredients concerned; and

(b) such other matters (if any) as the Secretary considers relevant.

(5A) If the Secretary refuses to make the recommendation, the Secretary must:

(a) notify the applicant in writing of his or her decision; and

(b) state in the notice the reasons for the decision.

Partial refund of evaluation fee in certain circumstances (5B) If:

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(a) an evaluation fee is prescribed for the purposes of paragraph (3)(b); and

(b) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which a decision under paragraph (4)(a) or (b) must be made; and

(c) the Secretary makes a decision under paragraph (4)(a) or (b) in relation to an application under subsection 26BD(1), but not within that period;

then 25% of the evaluation fee must be refunded to the applicant.

Deemed refusal of applications in certain circumstances (5C) If:

(a) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which a decision under paragraph (4)(a) or (b) must be made; and

(b) at the end of that period, the Secretary has not made a decision under paragraph (4)(a) or (b) in relation to an application under subsection 26BD(1);

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(5D) A notice under subsection (5C) may be given at any time before a decision under paragraph (4)(a) or (b) in relation to the application is made.

(5E) If a notice has been given under subsection (5C), this Act (except subsection 60(5)) has effect as if:

(a) the Secretary had decided not to make a recommendation under this section; and

(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

(c) the Minister's decision had been made on the day on which notice was given to the Secretary under subsection (5C).

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Minister may vary determination

(6) If the Secretary makes a recommendation under paragraph (4)(a), the Minister must:

(a) by legislative instrument, vary the section 26BB determination; or

(b) refuse to vary the section 26BB determination.

(7) In making a decision under subsection (6), the Minister must have regard to:

(a) the recommendation made under paragraph (4)(a); and

(b) such other matters (if any) as the Minister considers relevant.

Information may be given electronically

(9) A notice mentioned in subsection (3A) may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

26BF Permissible indications

(1) The Minister may, by legislative instrument, make a determination in relation to either or both of the following:

(a) indications;

(b) requirements in relation to indications.

Note: See paragraphs 26A(2)(fba), (fd) and (fe) (which deal with matters that a person seeking the listing of a medicine under section 26A must certify).

(2) In deciding whether to make a determination under subsection (1) in relation to a particular indication, the Minister may have regard to whether the indication is a therapeutic use that relates to one or more of the following:

(a) maintaining health;

(b) enhancing health;

(c) preventing a dietary deficiency;

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(d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury.

(3) Subsection (2) does not limit the matters to which the Minister may have regard in deciding whether to make a determination under subsection (1) in relation to a particular indication.

(4) Without limiting paragraph (1)(b), the requirements may relate to:

(a) the use of particular indications in specified circumstances; or

(b) the use of particular indications if certain specified conditions are met.

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicines.

(6) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under subsection (1) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

26BG Limitations on determination under section 26BF

(1) The Minister may, by legislative instrument, make a determination specifying indications that must not be covered by a determination under paragraph 26BF(1)(a).

(2) The determination may specify an indication either generally or in relation to specified circumstances.

(3) The Minister may, by legislative instrument, vary or revoke a determination under subsection (1).

26BH Variation of determination under section 26BF—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BF.

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26BJ Variation of determination under section 26BF—application by person

Application for recommendation to vary section 26BF determination

(1) A person may apply to the Secretary for a recommendation that the Minister vary a determination under section 26BF.

(2) An application under subsection (1) must:

(a) be made in accordance with a form approved, in writing, by the Secretary; and

(b) set out the recommendation sought; and

(c) be delivered to an office of the Department specified in the form; and

(d) be accompanied by the prescribed application fee (if any).

Limits on kinds of applications that can be made

(3) A person cannot make an application under subsection (1) for a recommendation the effect of which would be for the determination to cover any of the following:

(a) an indication specified in a determination under section 26BG;

(b) an indication that is or contains a restricted representation (within the meaning of Part 5-1);

(c) unless subsection (4) applies—an indication that is or contains a prohibited representation (within the meaning of Part 5-1);

(d) unless subsection (5) applies—an indication that refers to preventing, curing or alleviating a disease, ailment, defect or injury.

(4) For the purposes of paragraph (3)(c), this subsection applies if:

(a) the indication is a therapeutic use that relates to sun protection; and

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(b) the prohibited representation relates to the prevention of skin cancer; and

(c) the use of the prohibited representation is permitted under section 42DK.

(5) For the purposes of paragraph (3)(d), this subsection applies if the indication refers to:

(a) the prevention of a dietary deficiency; or

(b) the prevention of skin cancer or sun damage.

Further information about application for recommendation

(6) The Secretary may, by written notice given to a person who has made an application under subsection (1), require the person to:

(a) give the Secretary such further information in connection with the application as is specified in the notice; and

(b) do so within such reasonable time as is specified in the notice.

Lapsing of application for recommendation

(7) An application made under subsection (1) lapses if:

(a) the application contains information that is inaccurate or misleading in a material particular; or

(b) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

Decision on application for recommendation

(8) If:

(a) an application is made under subsection (1); and

(b) any applicable prescribed application fee has been paid; and

(c) if further information is required to be given under subsection (6) within a specified time—the information is given within that time;

the Secretary must decide whether to make the recommendation or refuse to make the recommendation.

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(9) In deciding whether to make the recommendation, the Secretary may have regard to whether the indication to which the application relates is a therapeutic use that relates to one or more of the following:

(a) maintaining health;

(b) enhancing health;

(c) preventing a dietary deficiency;

(d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury;

(e) sun protection.

(10) If the Secretary refuses to make the recommendation, the Secretary must:

(a) notify the applicant in writing of his or her decision; and

(b) state in the notice the reasons for the decision.

Minister may vary section 26BF determination

(11) If the Secretary makes a recommendation under subsection (8), the Minister must:

(a) by legislative instrument, vary the determination under subsection 26BF(1); or

(b) refuse to vary the determination.

(12) In deciding whether to vary a determination under subsection 26BF(1) to include an indication not already covered by the determination, the Minister may have regard to:

(a) the recommendation made under subsection (8) of this section; and

(b) whether the indication is a therapeutic use that relates to one or more of the matters in paragraphs (9)(a) to (e) of this section.

(13) Subsection (12) does not limit the matters to which the Minister may have regard in deciding whether to vary the determination.

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Applications or information may be given electronically

(14) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (6), may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

26C Certificates required in relation to patent infringement proceedings

(1) This section applies if:

(a) a person gives a certificate required under subsection 26B(1) in relation to therapeutic goods; and

(b) another person (the ***second person***) intends to commence proceedings under the *Patents Act 1990* against the person referred to in paragraph (1)(a) for infringement of a patent that has been granted in relation to the therapeutic goods (the ***proceedings***).

(2) The second person, before the date upon which the proceedings are commenced, must give to the Secretary and to the person referred to in paragraph (1)(a) the certificate required by subsection (3).

(3) The certificate required by this subsection is a certificate to the effect that the proceedings:

(a) are to be commenced in good faith; and

(b) have reasonable prospects of success; and

(c) will be conducted without unreasonable delay.

The certificate must be signed by, or on behalf of, the second person and must be in a form approved by the Secretary.

(4) For the purpose of paragraph (3)(b), proceedings have reasonable prospects of success if:

(a) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in

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addition to the fact of grant of the patent), for believing that he or she would be entitled to be granted final relief by the court against the person referred to in paragraph (1)(a) for infringement by that person of the patent; and

(b) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged, is valid; and

(c) the proceedings are not otherwise vexatious or unreasonably pursued.

(5) The person referred to in paragraph (1)(a), with leave of the court, or the Attorney-General, may apply to a prescribed court for an order that the second person pay to the Commonwealth a pecuniary penalty if the second person gives a certificate required under subsection (3) and:

(a) the certificate is false or misleading in a material particular; or

(b) the second person breaches an undertaking given in the certificate.

(5A) A pecuniary penalty ordered under subsection (5) must not exceed $10,000,000.

(6) When determining the extent of a pecuniary penalty to be ordered pursuant to subsection (5), the court must take into account:

(a) any profit obtained by the second person; and

(b) any loss or damage suffered by any person;

by reason of the second person exploiting the patent during the proceedings.

(7) For the avoidance of doubt, subsection (6) does not limit the matters the court may take into account when determining a pecuniary penalty ordered pursuant to subsection (5).

(8) If:

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(a) the second person has sought and obtained in the proceedings an interlocutory injunction restraining the person referred to in paragraph (1)(a) from infringing a patent; and

(b) section 26D does not apply; and

(c) a prescribed court declares that the second person has given a certificate required under subsection (3); and

(d) a prescribed court declares that:

(i) the certificate is false or misleading in a material particular; or

(ii) the second person has breached an undertaking given in the certificate;

the prescribed court may, pursuant to this section, order that the second person pay to the Commonwealth, a State or a Territory compensation for any damages sustained or costs incurred by the Commonwealth, a State or a Territory as a result of the grant of the interlocutory injunction.

(9) In this section:

prescribed court has the same meaning as in the *Patents Act 1990*.

26D Requirements for interlocutory injunction

(1) This section applies where:

(a) an applicant gives notice to a patentee in accordance with subparagraph 26B(1)(b)(iii); and

(b) the patentee and/or its exclusive licensee (in this section the party or parties is or are referred to as the ***patentee***) applies to a prescribed court for an interlocutory injunction to restrain the applicant from marketing the therapeutic goods the subject of the application on the ground that such conduct will constitute an infringement of its patent.

(2) An application for interlocutory relief in accordance with subsection (1) may not be instituted unless the patentee has first notified the Attorney-General of the Commonwealth, or of a State or of a Territory, in writing of the application.

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(3) The Attorney-General of the Commonwealth shall be deemed to be a party to any proceedings commenced in accordance with subsection (1) unless the Attorney-General gives written notice to the prescribed court that he or she does not desire to be a party.

(4) If an interlocutory injunction is granted pursuant to an application made as described in subsection (1) and:

(a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties thereto; or

(b) the principal proceedings are dismissed; and

(c) in either case, the prescribed court declares that:

(i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee or which ought reasonably have been known to the patentee:

(A) to believe that it would be granted final relief by the prescribed court against the applicant referred to in paragraph (1)(a) for infringement by that person of the patent; or

(B) (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged in the proceedings, would have a reasonable prospect of being held to be valid if challenged by the applicant referred to in paragraph (1)(a); or

(ii) the application for the interlocutory injunction was otherwise vexatious or not reasonably made or pursued;

the prescribed court may, in addition to any other relief which it believes should be granted to any person, make any of the orders described in subsection (5).

(5) If the prescribed court makes a declaration pursuant to paragraph (4)(c), the prescribed court may, pursuant to the usual undertaking as to damages given by the patentee to the prescribed court to obtain the interlocutory injunction:

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(a) assess and award compensation to the applicant referred to in paragraph (1)(a) against whom the interlocutory injunction was made:
(i) on the basis of an account of the gross profits of the patentee arising from the sale by it in Australia of the therapeutic goods the subject of the interlocutory injunction, during the period of the interlocutory injunction, without requiring the said applicant to establish or quantify its actual loss; or
(ii) on such other basis as the court determines to be appropriate; and
(b) award to the Commonwealth compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction; and
(c) award to a State or a Territory compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction.

(6) In this section:

prescribed court has the same meaning as in the *Patents Act 1990*.

27 Registration or listing number

(1) Where the Secretary includes therapeutic goods (other than grouped therapeutic goods) in the Register, the Secretary is to assign a unique registration or listing number to the goods.

(2) Where the Secretary includes grouped therapeutic goods in the Register, the Secretary is to assign a single, unique registration or listing number to the grouped therapeutic goods.

28 Conditions of registration or listing

(1) The registration or listing of therapeutic goods is subject to the conditions set out in a determination under subsection (2).

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(2) The Minister may, by legislative instrument, make a determination setting out conditions for the purposes of subsection (1), being conditions that relate to:

(a) the manufacture of the goods; or

(b) the custody, use, supply, disposal or destruction of the goods; or

(c) the keeping of records relating to the goods; or

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or

(e) such other matters relating to the goods as the Minister thinks appropriate.

(2A) Without limiting subsection (2), different conditions may be specified for:

(a) the registration of therapeutic goods; and

(aa) the provisional registration of medicine; and

(b) the listing of therapeutic goods; and

(c) different classes of therapeutic goods.

(2AA) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under subsection (2) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

(2B) If the Secretary includes therapeutic goods in the Register in relation to a person, the Secretary may, by notice in writing given to the person, impose conditions on the registration or listing of those goods.

(3) The Secretary may, by notice in writing given to the person in relation to whom therapeutic goods are registered or listed, impose new conditions on the registration or listing or vary or remove conditions imposed under subsection (2B) or this subsection.

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(3A) The Secretary's power under subsection (3) may be exercised at the request of the person concerned or of the Secretary's own motion. A request must be accompanied by the prescribed fee.

(4) The imposition or variation or removal of a condition under subsection (3) takes effect:

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(aa) in the case of an imposition or variation requested by the person, and to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day; or

(ab) in the case of a removal to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 28 days after the notice is given to the person.

(4A) For the purposes of paragraphs (4)(aa) and (ab), the earlier day must not be earlier than the day the notice is given to the person.

(5) In addition to any conditions imposed under subsection (1), (2B) or (3), the registration or listing of therapeutic goods (the ***subject goods***) is subject to the conditions that the person in relation to whom the subject goods are registered or listed will:

(aaa) if:

(i) the person proposes to make a change to the information included in the entry in the Register that relates to the subject goods; and

(ii) the information proposed to be changed is of a kind that relates to one or more of the matters referred to in paragraphs 25(1)(c) to (ja), 26(1)(c) to (n), 26A(2)(a) to (ja) or 26AB(2)(a) to (p) (as appropriate); and

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(iii) the Secretary would be required, under section 9D, to vary that entry, or to consider whether to vary that entry, in relation to the information proposed to be changed if the person made a request under that section for a variation of that entry;

make that request and not make the change unless the Secretary varies that entry in accordance with that request; and

(aa) not supply a batch of the subject goods in Australia, or export a batch of the subject goods from Australia, after the expiry date for the goods; and

(ab) not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register; and

(a) allow an authorised person:

(i) to enter, at any reasonable time, premises at which the person deals with the subject goods, complies with record-keeping requirements covered by paragraph (c) or (ca), or keeps documents that relate to the subject goods; and

(ii) while on those premises, to inspect those premises and any therapeutic goods on those premises and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods on those premises or any thing on those premises that relates to any therapeutic goods; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with paragraph (c) or (ca); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the subject goods; and

(b) if requested to do so by an authorised person, produce to the person such documents relating to the subject goods as the

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person requires and allow the person to copy the documents; and

(c) in relation to each batch of the subject goods—keep a record, at least until the end of the period of 12 months after the expiry date for the goods, of all of the manufacturers involved in the manufacture of that batch; and

(ca) comply, in relation to the subject goods, with any record-keeping requirements that are prescribed; and

(d) if requested to do so by an authorised person, make any record kept in compliance with paragraph (c) or (ca) available to the authorised person for inspection:

(i) at or before the time the authorised person requests, or (if the authorised person requests) immediately; and

(ii) either in electronic form or in paper form, as the authorised person requests; and

(e) comply, in relation to the subject goods, with any reporting requirements that are prescribed; and

(f) if a manufacturer who was not nominated as a manufacturer of the subject goods in the application for the registration or listing of the goods becomes a manufacturer of the goods— inform the Secretary in writing of that fact, no later than 10 working days after the manufacturer becomes a manufacturer of the goods; and

(g) if premises that were not nominated as premises to be used in the manufacture of the subject goods in the application become premises used in the manufacture of the goods— inform the Secretary in writing of that fact, no later than 10 working days after the premises are first used for that purpose; and

(h) deliver a reasonable number of samples of the subject goods if the Secretary so requests:

(i) within the period specified in the request (which must include at least 10 working days); and

(ii) in accordance with any other requirements specified in the request; and

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(i) comply, in relation to the subject goods, with a notice given to the person under subsection 25AA(1B).

(5B) The listing of a medicine under section 26A or 26AE is subject to a condition that:

(a) each step in the manufacture of the medicine that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step or who is exempt from the operation of Part 3-3 in relation to that step; and

(b) each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3), 26AB(4) or 28A(2).

(5C) Subsection (5B) does not apply if the medicine is exempt from the operation of Part 3-3.

(6) If in, or in connection with, an application for the listing of therapeutic goods, a claim (other than a claim that is an indication) is made by the applicant in relation to the goods, the listing of the goods is subject to the following conditions:

(a) a condition that the sponsor of the goods had, at the time when the claim was made, information or evidence that supported the claim and complied with the requirements (if any) specified in a determination made under subsection 26A(2B);

(b) a condition that the sponsor retains the information or evidence at all times while the goods remain listed;

(c) a condition that, at any time while the goods remain listed, the sponsor will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

(7) If:

(a) a medicine is listed under section 26A; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed,

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information or evidence that supports the indication and complies with the requirements (if any) specified in a determination under subsection 26A(2B);

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

(8) If:

(a) a medicine is listed under section 26AE; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication;

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

28A Certification of manufacturing steps outside Australia following application for listing

(1) The person in relation to whom medicine is listed under section 26A or 26AE may apply to the Secretary for a certification under this section of a step in the manufacture of the medicine that is to be carried out outside Australia.

Note: The listing of medicine is subject to the condition that each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3) or subsection (2) of this section: see subsection 28(5B).

(2) If an application is made to the Secretary under this section, the Secretary may, by writing, certify that the manufacturing and quality control procedures used in that step are acceptable. The Secretary must give the person written notice of the certification.

(3) In deciding whether to give the certification:

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(a) subsection 26A(4) applies in a way corresponding to the way in which it applies for the purposes of subsection 26A(3); and
(b) subsection 26AB(5) applies in a way corresponding to the way in which it applies for the purposes of subsection 26AB(4).

29 Duration of registration or listing

(1) Subject to this section, if goods are included in the Register in relation to a person, the goods remain so included until their registration or listing is cancelled under this Part.

Note: The goods are taken not to be included in the Register while their registration or listing is suspended: see section 29G.

Provisionally registered medicine

(2) If:
(a) a person makes an application for provisional registration of a medicine; and
(b) in relation to that application, the Secretary decides under subsection 25(3) to register the medicine; and
(c) the medicine is included in the Register in relation to the person;

then:
(d) the medicine is provisionally registered; and
(e) the medicine remains included in the Register for the provisional registration period, unless the medicine's registration is cancelled under this Part earlier.

Note: The medicine is taken not to be included in the Register while its registration is suspended: see section 29G.

(3) Subject to this section, the ***provisional registration period***, for a medicine that is provisionally registered because of an application that, under subsection 23AA(1), is taken to be an application for provisional registration of the medicine, is the period of 2 years starting on the day the registration commences.

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Note: Subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration.

(3A) Subject to this section, the ***provisional registration period***, for a medicine (the ***new medicine***) that is provisionally registered because of an application that, under subsection 23AA(2), is taken to be an application for provisional registration of the new medicine, is as follows:

(a) if, in relation to the new medicine, the day (the ***start day***) referred to in subsection 25AB(6) occurs in the period (the ***original period***) referred to in subsection (3) of this section in relation to the original medicine concerned—the period starting on the start day and ending at the end of the original period;

(b) if, in relation to the new medicine, the start day occurs in a period of extension of the original period that is granted under subsection (6)—the period starting on the start day and ending at the end of that extension period.

Note: Subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration.

Extension of provisional registration upon application

(4) The person in relation to whom the medicine is provisionally registered may make an application to the Secretary to extend the provisional registration period.

(5) The application must:

(a) be in a form approved, in writing, by the Secretary; and

(b) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and

(c) be made:

(i) if the medicine is provisionally registered because of an application that, under subsection 23AA(1), was taken to be an application for provisional registration of the medicine—at least 6 months before the provisional registration of the medicine is due to end; or

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(ii) if the medicine is provisionally registered because of an application that, under subsection 23AA(2), was taken to be an application for provisional registration of the medicine—at least 1 month before the provisional registration of the medicine is due to end; and

(d) be accompanied by the prescribed application fee.

(6) If:

(a) a person makes an application under subsection (4) in accordance with this section; and

(b) the medicine is provisionally registered because of an application that, under subsection 23AA(1), was taken to be an application for provisional registration of the medicine;

the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to:

(c) whether the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years starting on the day the provisional registration commenced; and

(d) such other matters (if any) as the Secretary considers relevant.

(6A) If:

(a) a person makes an application under subsection (4) in accordance with this section; and

(b) the medicine is provisionally registered because of an application that, under subsection 23AA(2), was taken to be an application for provisional registration of the medicine;

the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to such matters as the Secretary considers relevant.

(7) As soon as practicable after making a decision under subsection (6) or (6A), the Secretary must:

(a) give the applicant written notice of the decision; and

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(b) if the Secretary decides to extend the provisional registration period—specify in the notice the period of the extension (which must not exceed 2 years and may be less than the period sought by the applicant); and

(c) if the Secretary refuses to extend the provisional registration period—set out the reasons for the refusal in the notice.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(8) No more than 2 extensions may be granted in relation to a medicine on applications under subsection (4).

Note: Under subsection (9) the Secretary may extend the provisional registration period on his or her own initiative.

(8A) The Secretary must not, under subsection (6A), extend the provisional registration period applicable under subsection (3A) for the new medicine so that period would end more than 6 years after the provisional registration for the original medicine concerned commenced.

Effect on provisional registration of later section 23 application

(9) If:

(a) before the provisional registration period ends, the person in relation to whom the medicine is provisionally registered makes an application under section 23 for registration of the medicine; and

(b) the application is for the medicine to be included in the part of the Register for goods known as registered goods;

then the Secretary may, in connection with the application, end or extend the provisional registration period as the Secretary considers appropriate.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(10) In ending or extending, under subsection (9), the provisional registration period:

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(a) the Secretary must have regard to any matters prescribed by the regulations for the purposes of this paragraph; and
(b) the Secretary must ensure the provisional registration period continues while the Secretary is considering the application, unless the medicine's registration is cancelled under this Part; and
(c) the Secretary must not extend the provisional registration period so it would end more than 6 years after the provisional registration commenced, unless the extension is for the purposes of paragraph (b).

29A Criminal offence for failing to notify adverse effects etc. of goods

(1) As soon as a person in relation to whom therapeutic goods are registered or listed becomes aware of information of a kind mentioned in subsection (2) relating to the goods, the person must give the information to the Secretary in writing.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) The information with which subsection (1) is concerned is information of the following kinds:
(a) information that contradicts information already furnished by the person under this Act;
(b) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;
(c) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as the application for registration or listing of the goods or information already furnished by the person under this Act suggests;
(d) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

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29AA Civil penalty for failing to notify adverse effects etc. of goods

(1) A person contravenes this section if:

(a) therapeutic goods are registered or listed in relation to a person; and

(b) the person becomes aware of information of a kind mentioned in subsection (2) relating to the goods; and

(c) the person does not give the information to the Secretary in writing as soon as he or she becomes aware of it.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

(2) The information with which subsection (1) is concerned is information of the following kinds:

(a) information that contradicts information already given by the person under this Act;

(b) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;

(c) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as the application for registration or listing of the goods or information already given by the person under this Act suggests;

(d) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

29B Notification of adverse effects etc. where application withdrawn or lapses

(1) If an application for registration or listing of goods is withdrawn or lapses, the Secretary may give the applicant written notice requiring the applicant:

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(a) to inform the Secretary in writing whether the applicant is aware of any information of a kind mentioned in subsection 29A(2) or 29AA(2) relating to the goods; and
(b) if the applicant is aware of such information, to give the information to the Secretary in writing.

(2) Notice under subsection (1) may be given within 14 days after an application is withdrawn or lapses.

(3) A person must comply with the requirements of a notice under subsection (1) within 30 days after the notice is given to the person.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person must not, in purported compliance with a notice under subsection (1), give information that is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

29C Civil penalties for failing to notify adverse effects etc. where application withdrawn or lapses

Civil penalty for failing to comply with requirements of a notice

(1) A person contravenes this subsection if the person does not comply with the requirements of a notice under subsection 29B(1) within 30 days after the day on which the notice is given to the person. Maximum civil penalty:
(a) for an individual—3,000 penalty units; and
(b) for a body corporate—30,000 penalty units.

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Civil penalty for giving false or misleading information in purported compliance with requirements of a notice

(2) A person contravenes this subsection if the person, in purported compliance with a notice under subsection 29B(1), gives information that is false or misleading in a material particular. Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

29D Suspension of registration or listing

(1) The Secretary may, by written notice given to a person in relation to whom therapeutic goods are included in the Register, suspend the registration or listing of the goods if:

(a) the Secretary is satisfied that:

(i) there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register; and

(ii) it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

(b) the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2).

Notice of proposed suspension in some cases

(2) However, before suspending the registration or listing of the goods because of paragraph (1)(b), the Secretary must:

(a) inform the person by written notice that the Secretary proposes the suspension and set out the reasons for it; and

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(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(3) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

Period of suspension

(4) A notice under subsection (1) must specify the period of the suspension. The period must not exceed 6 months.

Note: Section 29E deals with when the suspension takes effect and extensions of the suspension.

Publication

(5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the suspension.

29E When suspension takes effect etc.

(1) A suspension under section 29D takes effect:

(a) if the notice under subsection 29D(1) states that the suspension is necessary to prevent a potential risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(2) The suspension has effect until:

(a) the Secretary revokes it under section 29F; or

(b) the end of:

(i) the period specified in the notice under subsection 29D(4); or

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(ii) if the period is extended under subsection (3) of this section, the period as so extended.

Extension of suspension

(3) The Secretary may, by written notice given to the person, extend the period specified in the notice under subsection 29D(4) by a further specified period not exceeding 6 months.

Publication

(4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the extension.

29F Revocation of suspension

(1) The Secretary must revoke a suspension under section 29D, by written notice given to the person in relation to whom the therapeutic goods are included in the Register, if the Secretary is satisfied that:
(a) the ground on which the registration or listing of the therapeutic goods was suspended no longer applies; and
(b) there are no other grounds for suspending the registration or listing of the therapeutic goods.

(2) The Secretary's power to revoke the suspension may be exercised:
(a) if the person in relation to whom the therapeutic goods are included in the Register applies in writing to the Secretary; or
(b) on the Secretary's own initiative.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

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Notice of refusal to revoke suspension

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:
(a) notify the applicant in writing of his or her decision; and
(b) state in the notice the reasons for the decision.

29G Effect of suspension

(1) If the registration or listing of therapeutic goods is suspended under section 29D, the goods are taken, for the purposes of this Act (other than sections 28, 29A, 29AA, 29E, 29F, 30 and 31), not to be included in the Register while the suspension has effect.

Note: Dealing in therapeutic goods that are not included in the Register may be an offence or may contravene a civil penalty provision: see Division 1.

(2) While the suspension has effect, the Secretary's power under section 30 to cancel the registration or listing of the therapeutic goods is not affected.

30 Cancellation of registration or listing

(1) The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:
(a) it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or
(b) the goods are exempt goods; or
(c) the person requests in writing the cancellation of the registration or listing; or
(d) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; or
(da) the person has refused or failed to comply with the condition to which the inclusion of the goods is subject under paragraph 28(5)(d):

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(i) if the person was requested under that paragraph to make the record in question available at or before a requested time—before the end of the period of 24 hours after that time; or

(ii) if the person was requested under that paragraph to make the record in question available immediately— within 24 hours after the request was made; or

(e) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (ca), (cb), (e), (fba), (fd), (fe) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) or (4A) are not fulfilled; or

(ea) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under paragraph 26AB(2)(a), (d), (e), (h) or (n) are incorrect or (if applicable) the requirements under subsection 26AB(4) or (6) are not fulfilled; or

(f) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the goods and the Secretary is satisfied that the contravention is significant; or

(fa) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the goods and the Secretary is satisfied that the contravention is significant; or

(fb) there is a breach, involving the goods, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 or 5-1A or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of the goods is misleading to a significant extent; or

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(g) the Secretary is satisfied that a statement made in, or in connection with, the application for registration or listing of the goods was false or misleading in a material particular; or

(h) the annual registration or listing charge is not paid within 28 days after it becomes payable.

(1AA) Paragraph (1)(fb) does not apply to medicines that are manufactured in Australia for export only, or are imported into Australia for export only.

(1A) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A or 26AE, cancel the listing of the medicine if:

(a) the medicine is not eligible for listing; or

(b) the medicine is exempt.

(1C) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

(b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under subsection 26A(2) or (2A) in relation to the medicine are incorrect; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

(1D) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26AE, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

(b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under

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subsection 26AB(2) or (3) in relation to the medicine are incorrect; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

(2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or

(aa) it appears to the Secretary that the presentation of the goods:

(i) in the case of registered goods—is not acceptable; or

(ii) in the case of listed goods—is unacceptable; or

(b) the goods have changed so that they have become separate and distinct from the goods as so included; or

(ba) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(b), (c), (d), (da), (f), (fa), (fb), (fc), (h), (i), (j), (ja) or (k) or subsection 26A(2A) are incorrect; or

(bab) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under paragraph 26AB(2)(b), (c), (f), (g), (i), (j), (k), (l), (m), (o), (p) or (q) or subsection 26AB(3) are incorrect; or

(c) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject (other than the condition under paragraph 28(5)(d)); or

(caa) all of the following subparagraphs apply:

(i) the Secretary gives the person a notice under section 31 that requires the person to give to the Secretary information, or to produce to the Secretary documents, relating to the goods;

(ii) subsection (1C) of this section does not apply to the notice;

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(iii) the person fails to comply with that notice within a further 14 days after the end of the period specified in that notice; or

(ca) the person has contravened subsection 29A(1) or 29AA(1) in relation to the goods; or

(d) the goods become required to be included in the other part of the Register; or

(e) the goods do not conform to a standard applicable to the goods; or

(eaa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the goods; or

(eab) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the goods; or

(ea) either of the following has not been complied with in relation to the goods:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or 5-1A or the regulations.

(3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person under subsection (2), the Secretary must:

(a) inform the person in writing that the Secretary proposes to cancel that registration or listing and set out the reasons for that proposed action; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed action.

(4) Where a person makes submissions in accordance with paragraph (3)(b), the Secretary is not to make a decision relating to

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the cancellation until the Secretary has taken the submissions into account.

(4A) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration of the goods if the Secretary becomes aware that protected information was used when evaluating the goods for registration.

(4B) The Secretary must, by notice in writing given to a person in relation to whom a medicine is listed under section 26AE, cancel the listing of the medicine if the Secretary becomes aware that restricted information was used when evaluating the medicine for listing.

(4C) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if the Secretary is satisfied that:

(a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those prohibitions; or

(b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those conditions.

(5) Where the Secretary cancels the registration or listing of goods in relation to a person, the goods cease to be registered or listed:

(a) if the cancellation is effected under subsection (1), (1A), (1C), (1D) or (4C)—on the day on which the notice of cancellation is given to the person; or

(b) in any other case—on the day specified in the notice, which must be at least 20 working days after the notice is given to the person.

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30A Revocation of cancellation of registration or listing upon request

(1) If:

(a) the Secretary cancels the registration or listing of therapeutic goods because of the request of a person made under paragraph 30(1)(c); and

(b) before the end of the period of 90 days beginning on the day the goods ceased to be registered or listed, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the request is accompanied by the prescribed application fee;

the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

30AA Revocation of cancellation of registration or listing—payment of annual registration or listing charge

(1) If:

(a) the Secretary cancels the registration or listing of therapeutic goods because the annual registration or listing charge was not paid within 28 days after it became payable (see paragraph 30(1)(h)); and

(b) before the end of the period of 90 days beginning on the day the goods ceased to be registered or listed, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual registration or listing charge has been paid; and

(d) the request is accompanied by the prescribed application fee;

the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

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30B Publication of cancellation of registration or listing

If the Secretary cancels the registration or listing of therapeutic goods under section 30, the Secretary must, as soon as practicable after the cancellation, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the cancellation.

30C Consultation with Gene Technology Regulator

(1) This section applies to an application for listing or registration of a therapeutic good under section 23 if:

(a) the therapeutic good is, or contains, a GM product or a genetically modified organism; and

(b) if the application is for registration—the application has passed preliminary assessment; and

(c) if the application is for the listing of a medicine under section 26AE—the application has passed preliminary assessment.

(2) Subject to subsection (5), the Secretary must give written notice to the Gene Technology Regulator:

(a) stating that the application has been made; and

(b) requesting the Gene Technology Regulator to give advice about the application.

(3) If the Secretary gives the Gene Technology Regulator a notice under subsection (2), the Gene Technology Regulator may give written advice to the Secretary about the application.

(4) The advice is to be given within the period specified in the notice.

(5) If an advice from the Gene Technology Regulator is in force under section 30D in relation to a class of therapeutic goods, the Secretary is not required to notify the Regulator under this section in relation to an application for listing or registration of a therapeutic good belonging to that class.

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30D Secretary may seek advice about classes of GM products or genetically modified organisms

(1) The Secretary may request advice from the Gene Technology Regulator in relation to:

(a) therapeutic goods that consist of, or that contain, a GM product belonging to a class of GM products specified in the request; or

(b) therapeutic goods that consist of, or that contain, a genetically modified organism belonging to a class of genetically modified organisms specified in the request.

(2) A request for advice under subsection (1) must specify the matters to which the advice is to relate.

(3) If the Secretary requests advice from the Gene Technology Regulator under subsection (1), the Gene Technology Regulator may provide written advice in relation to the matters specified in the request.

(4) If the Gene Technology Regulator gives advice to the Secretary under subsection (3), the advice remains in force until it is withdrawn by the Gene Technology Regulator by written notice given to the Secretary.

30E Secretary to take advice into account

If the Secretary receives advice from the Gene Technology Regulator:

(a) in response to a notice under section 30C within the period specified in the notice; or

(b) under section 30D;

the Secretary must:

(c) ensure that the advice is taken into account in making a decision on the application to which the notice relates, or on an application to which the advice under section 30D relates, as the case requires; and

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(d) inform the Gene Technology Regulator of the decision on the application.

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Division 2A—Public notification, and recall, of therapeutic goods

30EA Public notification, and recall, of therapeutic goods

(1) The Secretary may, in writing, impose requirements, relating to therapeutic goods, on a person if:

(a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the goods; and

(b) the person is referred to in the third column of that item.

Circumstances in which requirements may be imposed

Item	Circumstance relating to therapeutic goods	Person subject to requirements
1.	The goods are supplied while they are registered goods or listed goods, but the Secretary is satisfied that they do not conform with a standard applicable to the goods	The person in relation to whom the goods are included in the Register
2.	The goods are supplied while they are registered goods or listed goods, but the Secretary is satisfied that the manufacturing principles have not been observed in the manufacture of the goods	The person in relation to whom the goods are included in the Register
3.	The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but the Secretary is satisfied that they do not conform with a standard applicable to the goods	The person supplying the goods

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to therapeutic goods**	**Person subject to requirements**
4.	The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but the Secretary is satisfied that the manufacturing principles have not been observed in the manufacture of the goods	The person supplying the goods
4A.	The goods are supplied and the Secretary is satisfied that: (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply contravenes one or more of those prohibitions; or (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions	The person supplying the goods
5.	The goods are supplied in contravention of subsection 19B(1), (4) or (4A) or 19D(1)	The person supplying the goods
5A.	The goods are supplied while they are registered goods or listed goods, but it appears to the Secretary that: (a) the quality, safety or efficacy of the goods is unacceptable; or (b) in the case of registered goods—the presentation of the goods is not acceptable; or (c) in the case of listed goods—the presentation of the goods is unacceptable	The person in relation to whom the goods are included in the Register

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to therapeutic goods**	**Person subject to requirements**
6.	The goods are supplied while they are registered goods or listed goods, but one or more steps in the manufacture of the goods has been carried out by a manufacturer while the manufacturer did not hold a licence that was in force	The person in relation to whom the goods are included in the Register
6A.	The registration or listing of the goods has been suspended under this Part	The person in relation to whom the goods were included in the Register
7.	The registration or listing of the goods has been cancelled under this Part	The person in relation to whom the goods were included in the Register
8.	The goods are counterfeit (within the meaning of section 42E)	The person supplying the goods

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recall therapeutic goods that have been distributed;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstances referred to in paragraph (1)(a) have occurred in relation to therapeutic goods;

(ba) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to either or both of the following:

(i) therapeutic goods;

(ii) the circumstances referred to in paragraph (1)(a) in relation to therapeutic goods;

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(c) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or distribution of therapeutic goods;
(d) to notify the Secretary, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to the persons to whom therapeutic goods have been supplied.

(3) If the circumstances referred to in paragraph (1)(a) apply only to a batch of therapeutic goods, the Secretary may limit the imposition of the requirements to the therapeutic goods included in that batch.

(4) A requirement to recall therapeutic goods under this section does not apply to therapeutic goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person.

30EB Publication of requirements

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after imposing a requirement under section 30EA, a notice setting out particulars of the requirement.

30EC Criminal offences for non-compliance with requirements

(1) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a requirement imposed on the person under section 30EA; and
(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 30EA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 30EA.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

30ECA Civil penalty for non-compliance with requirements

A person contravenes this section if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 30EA.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

30ED Powers of suspension and cancellation unaffected

Imposition of a requirement under section 30EA does not affect the Secretary's power to suspend or cancel the registration or listing of therapeutic goods under this Part.

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30EE Saving of other laws

This Division is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

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Division 2B—Reporting medicine shortages and discontinuation of supply of medicine

30EF Reporting medicine shortages

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any shortage of the medicine in Australia at a particular time. The person must do so:

(a) for a shortage that has a critical impact at that time—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, of the shortage; or

(b) in any other case—before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the shortage.

Note: For ***reportable medicine***, see section 30EH. For ***shortage*** of a medicine in Australia, see section 30EI.

Critical impact

(2) The shortage of a medicine in Australia at a particular time has a ***critical impact*** if, at that time, the medicine is included in an instrument under section 30EJ.

(3) The shortage of a medicine in Australia at a particular time also has a ***critical impact*** if:

(a) either:

(i) at that time, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) at that time, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient quantities to meet the demand for the other registered goods that is likely to arise because of the shortage; and

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(b) the shortage has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(aa) specify the period of the shortage of the medicine in Australia; and

(b) contain any other information required by that form.

Note: For ***period*** of a shortage of a medicine in Australia, see section 30EIA.

(5) An approval of a form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Civil penalty

(6) A person contravenes this subsection if:

(a) the person is subject to a requirement under subsection (1); and

(b) the person contravenes the requirement.

Maximum civil penalty:

(a) for an individual—100 penalty units; and

(b) for a body corporate—1,000 penalty units.

Exceptions

(7) Subsection (6) does not apply if:

(a) paragraph (1)(a) and subsection (3) apply in relation to the shortage but subsection (2) does not; and

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(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the shortage; and

(c) the person complied with paragraph (1)(b) in relation to the shortage.

(8) A person is not subject to a requirement under subsection (1), in relation to a shortage (the ***relevant shortage***) of a medicine in Australia at a particular time, if:

(a) the person has complied with the requirement under subsection (1) in relation to a shortage (the ***notified shortage***) of the same medicine at an earlier time; and

(b) the period of the shortage of the medicine in respect of the notified shortage (including any change to that period) is the same as the period of the shortage of the medicine in respect of the relevant shortage.

Example: There is a shortage of a medicine in Australia on 1 January 2024 because, at a time in the 6 months after that day, the supply of the medicine in Australia will not meet demand for the medicine (see section 30EI). The period of the shortage of the medicine will start on 1 March 2024 and end on 31 March 2024 (see section 30EIA).

The person in relation to whom the medicine is included in the Register has notified the Secretary of the shortage under this section.

On 1 February 2024 the period of the shortage of the medicine changes to a period that will start on 1 May 2024 and end on 31 May 2024.

The person must notify the change to the period of the shortage (see subsection 30EFA(1)). The person is not required to notify, under this section, of another shortage of the same medicine in respect of that same period starting on 1 May 2024 and ending on 31 May 2024.

30EFA Reporting changes to the period of a medicine shortage and resolution of a medicine shortage

Reporting changes to the period of a shortage

(1) A person who has notified the period of a shortage of a medicine in Australia in accordance with section 30EF or this section must

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notify the Secretary of any change to that period.

The person must do so:

(a) if the shortage was first required to be notified in accordance with paragraph 30EF(1)(a)—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, of the change to that period; or

(b) in any other case—before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the change to that period.

Reporting the resolution of a shortage

(2) A person who has notified the period of a shortage of a medicine in Australia in accordance with section 30EF or this section must notify the Secretary of any resolution of the shortage. The person must do so:

(a) if the shortage was first required to be notified in accordance with paragraph 30EF(1)(a)—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, that the period of the shortage has ended; or

(b) in any other case—before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, that the period of the shortage has ended.

Notification requirements

(3) A notification under subsection (1) or (2) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) for a notification under subsection (1)—specify the period of the shortage of the medicine in Australia; and

(c) for a notification under subsection (2)—specify the day the period of the shortage of the medicine in Australia ended; and

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(d) contain any other information required by that form.

(4) An approval of a form may require or permit information to be given in accordance with specified software requirements:
(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

Civil penalty

(5) A person contravenes this subsection if:
(a) the person is subject to a requirement under subsection (1) or (2); and
(b) the person contravenes the requirement.

Maximum civil penalty:
(a) for an individual—100 penalty units; and
(b) for a body corporate—1,000 penalty units.

30EG Reporting discontinuation of supply of medicine

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any decision (the ***discontinuation decision***) of the person to permanently discontinue the supply of the medicine in Australia. The person must do so:
(a) if the discontinuation is likely to be of critical impact:
(i) at least 12 months before the discontinuation is proposed to occur; or
(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made; or
(b) in any other case:
(i) at least 6 months before the discontinuation is proposed to occur; or
(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made.

Note: For ***reportable medicine***, see section 30EH.

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Critical impact

(2) The discontinuation of the supply of a medicine in Australia is likely to be of ***critical impact*** if, when the discontinuation decision is made, the medicine is included in an instrument under section 30EJ.

(3) The discontinuation of the supply of a medicine in Australia is also likely to be of ***critical impact*** if:

(a) either:

(i) when the discontinuation decision is made, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) when the discontinuation decision is made, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient quantities to meet the demand for the other registered goods that is likely to arise because of the discontinuation; and

(b) the discontinuation has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain the information required by that form.

(5) An approval of a form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

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Civil penalty

(6) A person contravenes this subsection if:

(a) the person is subject to a requirement under subsection (1); and

(b) the person contravenes the requirement.

Maximum civil penalty:

(a) for an individual—100 penalty units; and

(b) for a body corporate—1,000 penalty units.

Exception

(7) Subsection (6) does not apply if:

(a) paragraph (1)(a) and subsection (3) apply in relation to the discontinuation but subsection (2) does not; and

(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the discontinuation; and

(c) the person complied with paragraph (1)(b) in relation to the discontinuation.

30EH What is a reportable medicine?

(1) For the purposes of this Act, registered goods are a ***reportable medicine*** if:

(a) the goods are medicine; and

(b) either:

(i) the medicine contains one or more substances included in Schedule 4 or 8 to the current Poisons Standard; or

(ii) the medicine is determined in an instrument under subsection (2).

(2) The Minister may, by legislative instrument, determine medicine for the purposes of subparagraph (1)(b)(ii).

(3) The Minister must not determine a medicine unless the Minister is satisfied of either or both of the following:

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(a) the medicine is critical to the health of patients in Australia;

(b) the notification to the Secretary of any shortage of the medicine, or of any decision to permanently discontinue the supply of the medicine, in Australia would be in the interests of public health.

30EI When is there a medicine shortage?

For the purposes of this Act, there is a ***shortage*** of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine.

30EIA What is the period of a medicine shortage?

The ***period*** of a shortage of a medicine in Australia is the period:

(a) starting on the day the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine; and

(b) ending on the day before the day the supply of that medicine in Australia will, or will be likely to, meet that demand.

30EJ Medicines Watch List

(1) The Minister may, by legislative instrument, determine medicine for the purposes of subsections 30EF(2) and 30EG(2).

(2) The Minister must not determine a medicine unless the Minister is satisfied that any shortage of the medicine, or any permanent discontinuation of the supply of the medicine, in Australia has the potential to result in:

(a) significant morbidity in patients in Australia; or

(b) the death of one or more patients in Australia.

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Division 2C—Substitution of prescription medicine by pharmacists

30EK Minister may declare a serious scarcity of medicine

(1) The Minister may, by legislative instrument:

(a) declare that there is a serious scarcity of specified medicine (the ***scarce medicine***) across the whole or a specified part or parts of Australia; and

(b) specify the medicine (the ***substitutable medicine***) that pharmacists are permitted to dispense in substitution for the scarce medicine and specify the circumstances in which that substitution is permitted.

Note 1: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

Note 2: For variation and revocation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

Pre-conditions to making instrument

(2) The Minister may make an instrument under subsection (1) only if the Minister is satisfied:

(a) that either or both of the following apply:

(i) the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine;

(ii) there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine; and

(b) that there is a significant risk of adverse health consequences for patients in Australia if those patients are unable to take the scarce medicine; and

(c) of any other matters prescribed by the regulations for the purposes of this paragraph.

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Kind of medicine that can be covered by instrument

(3) The scarce medicine, and the substitutable medicine, must be medicine:

(a) that contains one or more substances included in Schedule 4 to the current Poisons Standard; and

(b) that does not contain any substances included in Schedule 8 to that standard.

Suitability of substitutable medicine

(4) Without limiting paragraph (1)(b), the circumstances may relate to:

(a) the class of persons for whom the substitutable medicine is suitable; or

(b) the class of persons for whom the substitutable medicine is not suitable.

Period instrument in force

(5) Unless sooner revoked, an instrument under subsection (1) remains in force for the period specified in the instrument.

Note: For variation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

30EL Substitution of prescription medicine by pharmacists

If:

(a) an instrument is in force under subsection 30EK(1); and

(b) under a law of a State or Territory, a pharmacist is authorised to dispense medicine (the ***scarce medicine***) covered by paragraph 30EK(1)(a) to a person;

then, despite any law of a State or Territory, the pharmacist may dispense medicine covered by paragraph 30EK(1)(b) to that person in substitution for the scarce medicine, provided that the substitution is in the circumstances specified in the instrument under subsection 30EK(1).

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Division 3—General

30F Criminal offences for goods exempt under section 18A not conforming to standards etc.

(1) This section applies if:

(a) therapeutic goods of a particular kind are exempt under section 18A; and

(b) a person supplies a batch of goods of that kind; and

(c) the Secretary is satisfied that the goods included in that batch:

(i) do not conform to a standard applicable to goods of that kind; or

(ii) are otherwise not fit to be used for their intended purposes.

(2) The Secretary may, by written notice given to the person, require the person to take steps to recall the goods included in that batch (except any of those goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person).

(3) The notice may specify one or more of the following requirements:

(a) the steps to be taken to recall the goods;

(b) the manner in which the steps are to be taken;

(c) a reasonable period within which the steps are to be taken.

(4) The Secretary must, as soon as practicable after giving the notice, cause particulars of it to be published in the *Gazette* or on the Department's website.

Written notice is not a legislative instrument

(4A) A written notice given to a person by the Secretary under this section is not a legislative instrument.

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Offences

(4B) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person failed to comply with that requirement.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (5) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(5) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(6) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

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(b) the notice specifies a particular requirement mentioned in subsection (3); and
(c) the person fails to comply with that requirement.

Penalty: 100 penalty units.

(6A) An offence against subsection (6) is an offence of strict liability.

Saving of other laws

(7) This section is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

30FA Civil penalty for goods exempt under section 18A not conforming to standards etc.

A person contravenes this section if:
(a) the Secretary gives a notice to the person under subsection 30F(2); and
(b) the notice specifies a particular requirement mentioned in subsection 30F(3); and
(c) the person does not comply with the requirement.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

30G Disposal of unused goods exempt under section 18A

(1) This section applies to particular therapeutic goods if:
(a) an exemption in relation to those goods under section 18A ceases to have effect otherwise than because those goods have become registered goods or listed goods (see paragraph 18A(5)(a)); and
(b) those goods have not been used before the exemption so ceases to have effect.

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(2) The Secretary may arrange for the disposal of any of those goods in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which those goods are to be stored, supplied, destroyed, exported or otherwise disposed of.

(4) A method set out in the regulations under subsection (3) must not enable or permit any benefit to be conferred on a person (including the Commonwealth) other than the owner of those goods.

30H Record for goods exempt under section 18A

(1) A person commits an offence if:
(a) there are therapeutic goods that are exempt under section 18A; and
(b) a condition of the exemption:
(i) requires the person to keep a record about those goods; or
(ii) specifies the manner in which the person must keep the record; and
(c) the person does an act or omits to do an act in relation to those goods; and
(d) the act or omission results in the breach of that condition of the exemption.

Penalty: 240 penalty units.

(2) Strict liability applies to paragraph (1)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(3) A person commits an offence if:
(a) there are therapeutic goods that are exempt under section 18A; and
(b) a condition of the exemption:
(i) requires the person to keep a record about those goods; or

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(ii) specifies the manner in which the person must keep the record; and

(c) the person does an act or omits to do an act in relation to those goods; and

(d) the act or omission results in the breach of that condition of the exemption.

Penalty: 60 penalty units.

(4) An offence under subsection (3) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

31 Secretary may require information or documents

(1) The Secretary may, by notice in writing given to a person:

(aa) who is an applicant for the registration of therapeutic goods; or

(ab) in relation to whom therapeutic goods are registered; or

(ac) in relation to whom therapeutic goods were, at any time during the previous 5 years, registered;

require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in the notice, information or documents relating to one or more of the following:

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods;

(d) the quality of the goods;

(e) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(f) the presentation of the goods;

(g) the safety and efficacy of the goods for the purposes for which they are to be used;

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(ga) whether the goods comply with conditions (if any) on the registration of the goods;

(gb) the conformity of the goods to a standard applicable to the goods;

(h) whether either of the following has not been complied with in relation to the goods:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or 5-1A or the regulations;

(ha) if the goods are registered in relation to the person—whether the goods are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(hb) if the goods are registered in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those prohibitions;

(hc) if the goods are registered in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those conditions;

(j) the regulatory history of the goods in another country;

(ja) if the goods are a reportable medicine and the medicine is registered in relation to the person:

(i) whether or not there is a shortage of the medicine in Australia; or

(ii) if there is a shortage of the medicine in Australia—the shortage; or

(iii) any decision of the person to permanently discontinue the supply of the medicine in Australia;

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(k) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

(1A) If a notice is given under subsection (1) to a person covered by paragraph (1)(ac), then paragraphs (1)(a) to (k) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the therapeutic goods were registered.

(1B) If:

(a) a person makes an application under section 23 for the registration of therapeutic goods in accordance with a form referred to in paragraph 23B(2)(a); and

(aa) the application has passed preliminary assessment; and

(b) the form is described as a pre-submission planning form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the application;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so specified is taken to be a reasonable time for the purposes of subsection (1).

(1C) If:

(a) the person in relation to whom therapeutic goods are registered makes a request under subsection 9D(3) in accordance with a form referred to in subsection 9D(6); and

(b) the form is described as a pre-submission planning form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the request;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so

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specified is taken to be a reasonable time for the purposes of subsection (1).

(2) The Secretary may, by notice in writing given to a person:

(aa) who is an applicant for the listing of therapeutic goods; or (ab) in relation to whom therapeutic goods are listed; or

(ac) in relation to whom therapeutic goods were, at any time during the previous 5 years, listed;

require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in the notice, information or documents relating to one or more of the following:

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods; (ca) the quality of the goods;

(d) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(e) the presentation of the goods;

(f) the safety of the goods for the purposes for which they are to be used;

(fa) if the goods are listed under section 26A—any of the matters covered by a certification by the person under subsection 26A(2) or (2A) in relation to the medicine;

(fab) if the goods are or were listed under section 26AE—any of the matters covered by a certification by the person under subsection 26AB(2) or (3) in relation to the medicine;

(fac) if the goods are or were listed under section 26AE—the efficacy of the goods in relation to the purposes for which they are to be used;

(fb) whether the goods comply with conditions (if any) on the listing of the goods;

(g) the conformity of the goods to a standard applicable to the goods;

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(gaa) whether either of the following has not been complied with in relation to the goods:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or 5-1A or the regulations;

(ga) if the goods are listed in relation to the person—whether the goods are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(gb) if the goods are listed in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those prohibitions;

(gc) if the goods are listed in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those conditions;

(h) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

(2A) If a notice is given under subsection (2) to a person covered by paragraph (2)(ac), then paragraphs (2)(a) to (h) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the therapeutic goods were listed.

(3) An approval of a form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(4) A person commits an offence if:

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(a) either:

(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or

(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and

(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(4A) Subsection (4) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (4A). See subsection 13.3(3) of the *Criminal Code*.

(4B) A person commits an offence if:

(a) either:

(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or

(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(5) An offence against subsection (4B) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(5AA) Subsection (4B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5AA): see subsection 13.3(3) of the *Criminal Code*.

(5A) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or a document in compliance or purported compliance with the notice; and

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(c) the information or document is false or misleading in a material particular; and

(d) either:

(i) the use of the therapeutic goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the therapeutic goods, if the therapeutic goods were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (6) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(6) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(7) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

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(8) An offence against subsection (7) is an offence of strict liability.

31AAA Civil penalty for providing false or misleading information or documents in relation to therapeutic goods

A person contravenes this section if:

(a) the person is given a notice under section 31 in relation to therapeutic goods; and

(b) the person gives information or a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

31A Secretary may require information etc. about goods exempt under section 18

Exempt goods for use for experimental purposes in humans

(1) If therapeutic goods are exempt under subsection 18(1) from the operation of this Part (except this section and sections 31C to 31F) to allow for their use for experimental purposes in humans, the Secretary may give the sponsor of the goods a written notice requiring the sponsor to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

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Statement by medical practitioner about medicine

(2) If a medicine is exempt under subsection 18(1) from the operation of this Part (except this section and sections 31C to 31F) because a medical practitioner has signed a statement in accordance with regulation 12A of the *Therapeutic Goods Regulations 1990*, the Secretary may give the medical practitioner a written notice requiring the medical practitioner to give to the Secretary specified information or documents relating to one or more of the following:

(a) the condition of the person to whom the medicine is to be given or is given;

(b) the supply of the medicine;

(c) the handling of the medicine;

(d) the monitoring of the supply of the medicine;

(e) the results of the supply of the medicine;

(f) any other matter prescribed by the regulations for the purposes of this paragraph in relation to medicines of that kind.

Compliance period

(3) A notice under subsection (1) or (2) must specify a reasonable period within which the person to whom the notice is given must comply with it. The period must be at least 14 days starting on the day on which the notice is given.

Information may need to be given in accordance with specified software requirements

(4) A notice under subsection (1) or (2) may require information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

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31AA Secretary may require information etc. about goods exempt under section 18A

(1) This section applies to a person who is required to comply with a condition of an exemption of therapeutic goods under section 18A.

(2) The Secretary may, by written notice given to the person, require the person to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of any of those goods;

(b) the handling of any of those goods;

(c) the monitoring of the supply of any of those goods;

(d) the results of the supply of any of those goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph.

Compliance period

(3) The notice must specify a reasonable period within which the person must comply with it. The period must be at least 14 days starting on the day on which the notice is given.

Information may need to be given in accordance with specified software requirements

(4) The notice may require information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

31B Secretary may require information relating to approvals and authorities under section 19

Approval under subsection 19(1)

(1) The Secretary may give to a person who is granted an approval under subsection 19(1) in relation to specified therapeutic goods a written notice requiring the person to give to the Secretary

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specified information or documents relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Approval under subsection 19(1)—use by another person

(2) The Secretary may give to a person using specified therapeutic goods that are the subject of an approval granted to someone else under paragraph 19(1)(b) a written notice requiring the person to give to the Secretary specified information or documents relating to either of both of the following:

(a) the use of the goods;

(b) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Authority under subsection 19(5)

(3) The Secretary may give to a person who is granted an authority under subsection 19(5) in relation to specified therapeutic goods, or a specified class of therapeutic goods, a written notice requiring the person to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

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Authority under subsection 19(7A) rules

(3A) If a person is authorised, by subsection 19(7A) rules, to supply therapeutic goods, the Secretary may give the person a written notice requiring the person to give the Secretary specified information or documents relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Compliance period

(4) A notice under subsection (1), (2), (3) or (3A) must specify a reasonable period within which the person to whom the notice is given must comply with it. The period must be at least 14 days starting on the day on which the notice is given.

Information may need to be given in accordance with specified software requirements

(5) A notice under subsection (1), (2), (3) or (3A) may require information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

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31BA Secretary may require information about therapeutic goods approved under section 19A

(1) The Secretary may give to a person who is granted an approval under subsection 19A(1), (1A), (2), (2A) or (2B) in relation to specified therapeutic goods a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations.

Compliance

(2) A person given a notice under subsection (1) must give the information, or produce the documents, to the Secretary:

(a) within the period specified in the notice (which must not be less than 14 days after the day the notice is given); and

(b) in the form specified in the notice.

(3) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

31C Criminal offences for failing to give information or documents sought under section 31A, 31AA, 31B or 31BA

(1) A person commits an offence if:

(a) the person is given a notice under section 31A, 31AA, 31B or 31BA; and

(b) the person fails to comply with the notice.

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Penalty: 400 penalty units.

(2) A person commits an offence if:

(a) the person is given a notice under section 31A, 31AA, 31B or 31BA; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

31D False or misleading information

(1) A person to whom a notice is given under section 31A, 31AA, 31B or 31BA commits an offence if:

(a) the person gives information to the Secretary in compliance or purported compliance with the notice; and

(b) the person does so knowing that the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(1A) A person to whom a notice is given under section 31A, 31AA, 31B or 31BA commits an offence if:

(a) the person gives information to the Secretary in compliance or purported compliance with the notice; and

(b) the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

Penalty: 100 penalty units.

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(1B) An offence against subsection (1A) is an offence of strict liability.

(2) Subsection (1) or (1A) does not apply as a result of subparagraph (1)(b)(i) or (1A)(b)(i) if the information is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2): see subsection 13.3(3) of the *Criminal Code*.

(3) Subsection (1) or (1A) does not apply as a result of subparagraph (1)(b)(ii) or (1A)(b)(ii) if the information did not omit any matter or thing without which the information is misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3): see subsection 13.3(3) of the *Criminal Code*.

31E False or misleading documents

(1) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the person does so knowing that the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 31A, 31AA, 31B or 31BA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(1A) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 31A, 31AA, 31B or 31BA.

Penalty: 100 penalty units.

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(1B) An offence against subsection (1A) is an offence of strict liability.

(2) Subsection (1) or (1A) does not apply if the document is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2): see subsection 13.3(3) of the *Criminal Code*.

(3) Subsection (1) or (1A) does not apply to a person who produces a document if the document is accompanied by a written statement signed by the person or, in the case of a body corporate, by a competent officer of the body corporate:

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and

(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3): see subsection 13.3(3) of the *Criminal Code*.

31F Self-incrimination

(1) A person is not excused from giving information or a document under a notice given under section 31, 31A, 31AA, 31B or 31BA on the ground that the giving of the information or document would tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given; or

(b) the giving of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, subsection 31(5A), (6) or (7) or section 31D or 31E; or

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(e) civil proceedings, except proceedings under section 42Y for a contravention of section 31AAA.

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Part 3-2A—Biologicals

Division 1—Preliminary

32 What this Part is about

This Part regulates biologicals. It does this by providing a process for including biologicals in the Register and providing for enforcement through criminal offences and civil penalties.

This Part provides for the following administrative processes:

(a) exempting biologicals from the requirement to be included in the Register;

(b) making the inclusion of biologicals in the Register subject to conditions;

(c) suspending or cancelling entries of biologicals from the Register;

(d) requiring public notification of problems with biologicals, and recall of biologicals;

(e) obtaining information or documents about biologicals.

32A Meaning of *biological*

(1) Subject to subsection (3), a ***biological*** is a thing that:

(a) either:

(i) comprises, contains or is derived from human cells or human tissues; or

(ii) is specified under subsection (2); and

(b) is represented in any way to be, or is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:

(i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or

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(ii) for use in making a medical diagnosis of the condition of a person; or

(iii) for use in influencing, inhibiting or modifying a physiological process in persons; or

(iv) for use in testing the susceptibility of persons to a disease or ailment; or

(v) for use in the replacement or modification of parts of the anatomy in persons.

(2) The Secretary may, by legislative instrument, specify things for the purposes of subparagraph (1)(a)(ii).

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

(3) The Secretary may, by legislative instrument, determine that a specified thing is not a biological for the purposes of this Act.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

32AA Biological classes

The regulations may prescribe different classes of biologicals.

Note 1: The regulations may prescribe the circumstances in which a biological included in a class of biologicals is separate and distinct from other biologicals: see section 32AB.

Note 2: The Secretary may approve different application forms for different classes of biologicals: see section 32DDA.

32AB When biologicals are separate and distinct from other biologicals

(1) The regulations may prescribe the circumstances in which a biological included in a specified class of biologicals is separate and distinct from other biologicals.

(2) The regulations may make different provision in relation to different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

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Note: The Secretary may cancel the entry of a biological from the Register if the biological has changed so that it has become separate and distinct from the biological as so included: see subsection 32GC(1).

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Division 2—Main criminal offences and civil penalties

32B What this Division is about

This Division contains criminal offences and civil penalties relating to the import, export, manufacture, supply and use of biologicals.

32BA Criminal offences for importing a biological

(1) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person; and

(c) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

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Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

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(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;
(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the importation.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) Subsection (1) does not apply if:
(a) harm or injury did not, will not, or is not likely to, directly result from:
(i) the quality, safety or efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or
(iii) the improper use of the biological; or
(b) harm or injury would not, or would not be likely to, directly result from:
(i) the quality, safety or efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or
(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

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32BB Criminal offences for exporting a biological

(1) A person commits an offence if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological; and

(c) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

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(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:
(a) the person exports from Australia a biological for use in humans; and
(b) none of the following subparagraphs applies:
(i) the biological is included in the Register in relation to the person;
(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the exportation.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

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(6) Subsection (1) does not apply if:

(a) harm or injury did not, will not, or is not likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BBA Treating biologicals as prohibited imports or exports

If:

(a) the importation or exportation of a biological is an offence under subsection 32BA(1), (4) or (4A) or 32BB(1), (4) or (4A); and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the biological included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act; as the case requires.

32BC Criminal offences for manufacturing a biological

(1) A person commits an offence if:

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(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB; and

(c) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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(4A) A person commits an offence if:

(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the manufacture.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) Subsection (1) does not apply if:

(a) harm or injury did not, will not, or is not likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological.

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Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BD Criminal offences for supplying a biological

(1) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological; and

(c) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

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(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;
(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;
(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the supply.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) Subsection (1) does not apply if:
(a) harm or injury did not, will not, or is not likely to, directly result from:
(i) the quality, safety or efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or
(iii) the improper use of the biological; or
(b) harm or injury would not, or would not be likely to, directly result from:
(i) the quality, safety or efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or

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(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BE Notice required to adduce evidence in support of exception to offences

(1) If:

(a) a defendant is committed for trial for an offence against subsection 32BA(1), 32BB(1), 32BC(1) or 32BD(1); or

(b) an offence against subsection 32BA(1), 32BB(1), 32BC(1) or 32BD(1) is to be heard and determined by a court of summary jurisdiction;

the committing magistrate or the court must:

(c) inform the defendant of the requirements of this section; and

(d) cause a copy of this section to be given to the defendant.

(2) A defendant must not, without leave of the court, adduce evidence in support of the exception under subsection 32BA(6), 32BB(6), 32BC(6) or 32BD(6) unless the defendant gives notice of particulars of the exception:

(a) if paragraph (1)(a) applies—more than 21 days before the trial begins; or

(b) if paragraph (1)(b) applies—more than 21 days before the hearing of the offence begins.

(3) A defendant must not, without leave of the court, call any other person to give evidence in support of the exception unless:

(a) the notice under subsection (2) includes the name and address of the person or, if the name and address is not known to the defendant at the time the defendant gives the notice, any information in the defendant's possession that might be of material assistance in finding the person; and

(b) if the name or the address is not included in the notice—the court is satisfied that the defendant before giving the notice took, and after giving the notice continued to take, all reasonable steps to ascertain the name or address; and

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(c) if the name or address is not included in the notice, but the defendant subsequently ascertains the name or address or receives information that might be of material assistance in finding the person—the defendant immediately gives notice of the name, address or other information, as the case may be; and

(d) if the defendant is told by or on behalf of the prosecutor that the person has not been found by the name, or at the address, given by the defendant:

(i) the defendant immediately gives notice of any information in the defendant's possession that might be of material assistance in finding the person; and

(ii) if the defendant later receives any such information

— the defendant immediately gives notice of the information.

(4) A notice purporting to be given under this section on behalf of the defendant by the defendant's legal practitioner is, unless the contrary is proved, taken as having been given with the authority of the defendant.

(5) Any evidence tendered to disprove that the exception applies may, subject to direction by the court, be given before or after evidence is given in support of the exception.

(6) A notice under this section must be given in writing to the Director of Public Prosecutions. A notice is taken as having been given if it is:

(a) delivered to or left at an office of the Office of the Director of Public Prosecutions; or

(b) sent by certified mail addressed to the Director of Public Prosecutions at an office of the Office of the Director of Public Prosecutions.

(7) In this section:

Director of Public Prosecutions means a person holding office as, or acting as, the Director of Public Prosecutions under the *Director of Public Prosecutions Act 1983*.

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32BF Civil penalties for importing, exporting, manufacturing or supplying a biological

Importing a biological for use in humans

(1) A person contravenes this subsection if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exporting a biological for use in humans

(2) A person contravenes this subsection if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

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(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Manufacturing a biological for use in humans

(3) A person contravenes this subsection if:
(a) the person manufactures in Australia a biological for use in humans; and
(b) none of the following subparagraphs applies:
(i) the biological is included in the Register in relation to the person;
(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Supplying a biological for use in humans

(4) A person contravenes this subsection if:
(a) the person supplies in Australia a biological for use in humans; and

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(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception if person was not the sponsor of the biological

(5) Subsection (1), (2), (3) or (4) does not apply if the person proves that he or she was not the sponsor of the biological at the time of the importation, exportation, manufacture or supply, as the case may be.

Civil penalty relating to the supply of biologicals included in the Register

(6) A person contravenes this subsection if:

(a) a biological is included in the Register in relation to the person; and

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(b) the biological is of a kind prescribed by the regulations for the purposes of this paragraph; and

(c) the person supplies the biological in Australia; and

(ca) the person does not have the consent in writing of the Secretary; and

(d) the biological number of the biological is not set out on the label of the biological in the prescribed manner.

Maximum civil penalty:

(a) for an individual—200 penalty units; and

(b) for a body corporate—2,000 penalty units.

Application of the Customs Act 1901

(7) If:

(a) the importation or exportation of a biological contravenes subsection (1) or (2); and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the biological included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act; as the case requires.

Decisions on whether to give consent

(8) The Secretary must, as soon as practicable after making a decision to give a consent mentioned in subsection (6), cause particulars of the decision to be published on the Department's website.

(9) The Secretary must, within 28 days after making a decision to refuse to give a consent mentioned in subsection (6), notify the applicant in writing of the decision and of the reasons for the decision.

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(10) The Secretary is not required to consider giving an applicant a consent mentioned in subsection (6) unless the applicant has paid the fee (if any) that is prescribed by the regulations for the processing of the applicant's application for such a consent.

32BG Criminal offences and civil penalty relating to a failure to notify the Secretary about manufacturing

Criminal offences

(1) A person commits an offence if:

(a) the person:

(i) imports a biological into Australia for use in humans; or

(ii) exports a biological from Australia for use in humans; or

(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(1A) A person commits an offence if:

(a) the person:

(i) imports a biological into Australia for use in humans; or

(ii) exports a biological from Australia for use in humans; or

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(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

Civil penalty

(2) A person contravenes this subsection if:

(a) the person:

(i) imports a biological into Australia for use in humans; or

(ii) exports a biological from Australia for use in humans; or

(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

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Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Definition

(3) For the purposes of this section:

(a) a manufacturer is ***properly notified*** to the Secretary if:

(i) the manufacturer was nominated, as a manufacturer of the biological, in an application for inclusion of the biological in the Register; or

(ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the biological; and

(b) premises are ***properly notified*** to the Secretary if:

(i) the premises were nominated, as premises used in the manufacture of the biological, in an application for inclusion of the biological in the Register; or

(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the biological.

32BH Criminal offence relating to wholesale supply

A person commits an offence if:

(a) the person supplies a biological in Australia for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an

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approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological; and

(c) the person to whom the biological is supplied is not the ultimate consumer of the biological.

Penalty: 120 penalty units.

32BI Criminal offence for using a biological not included in the Register

(1) A person commits an offence if:

(a) the person uses a biological; and

(b) the biological is used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);

(v) the person uses the biological in accordance with an approval under subsection 32CK(1);

(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;

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(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A); and

(d) either:

(i) if the person used the biological in the treatment of that other person—the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to that other person; or

(ii) if the person used the biological solely for experimental purposes in humans—the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any of those humans.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(4) A person commits an offence if:

(a) the person uses a biological; and

(b) the biological is used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);

(v) the person uses the biological in accordance with an approval under subsection 32CK(1);

(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;

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(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A).

Penalty: 500 penalty units.

(5) A person commits an offence if:
(a) the person uses a biological; and
(b) the biological is used:
(i) in the treatment of another person; or
(ii) solely for experimental purposes in humans; and
(c) none of the following subparagraphs applies:
(i) the biological is included in the Register;
(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);
(v) the person uses the biological in accordance with an approval under subsection 32CK(1);
(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;
(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A).

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

32BJ General criminal offences relating to this Part

Including incorrect biological number on containers etc.

(1) A person commits an offence if:
(a) the person sets out or causes to be set out, on a container or package that contains a biological or on a label of a

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biological, a number that purports to be the biological number of the biological; and

(b) the number is not that biological number. Penalty: 60 penalty units.

(2) For the purposes of subsection (1), ***number*** includes any combination of one or more of the following:

(a) numbers;

(b) letters;

(c) symbols.

Advertising biological for an indication

(2A) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion; and

(d) either:

(i) the use of the biological for the advertised indication has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological for the advertised indication, if the biological were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2B) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Penalty: 100 penalty units.

(3A) An offence against subsection (3) is an offence of strict liability.

32BK Civil penalty for making misrepresentations about biologicals

(1) A person contravenes this section if:

(a) the person makes a representation of a kind referred to in subsection (2); and

(b) the representation is false or misleading.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

(2) Subsection (1) applies to the following representations:

(a) representations that a biological is included in the Register;

(b) representations that a person is exempt under subsection 32CA(1) in relation to a biological or that a biological is exempt under subsection 32CA(2);

(c) representations that a biological is exempt under section 32CB;

(d) representations that a biological is the subject of an approval under subsection 32CK(1);

(e) representations that a biological is the subject of an authority under subsection 32CM(1) or (7A);

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(f) representations that a biological is the subject of an approval under subsection 32CO(1), (1A) or (2).

32BL Civil penalty for advertising biological for an indication

A person contravenes this section if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 3—Exemptions

Subdivision A—Preliminary

32C What this Division is about

There are 4 kinds of exemptions in relation to biologicals:

(a) exemptions of biologicals under the regulations; and

(b) exemptions of biologicals to deal with emergencies; and

(c) exemptions of biologicals for special and experimental uses; and

(d) exemptions of biologicals where substitutes are unavailable.

Subdivision B—Exempting biologicals under the regulations

32CA Exempt biologicals

(1) The regulations may exempt specified persons from the operation of Division 4 in relation to specified biologicals.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

(2) The regulations may exempt specified biologicals from the operation of Division 4.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

(3) An exemption under this section may be subject to conditions that are prescribed in the regulations.

Note: There are criminal offences and a civil penalty related to the breach of a condition of an exemption: see sections 32CP and 32CQ.

(5) If the regulations revoke an exemption, the revocation takes effect on the day specified in the regulations. The day must not be earlier

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than 28 days after the day on which the regulations revoking the exemption take effect.

Subdivision C—Exempting biologicals to deal with emergencies

32CB Minister may make exemptions

(1) The Minister may, by writing, exempt specified biologicals from the operation of Division 4.

Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Note 2: There are criminal offences and a civil penalty relating to biologicals exempt under this section not conforming to standards etc.: see section 32CJ.

(1A) The Minister may make an exemption under subsection (1) only if the Minister is satisfied of the matter in subsection (2) or (2A).

(2) The matter in this subsection is that in the national interest, the exemption should be made so that:

(a) the biologicals may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency; or

(b) the biologicals can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred.

(2A) The matter in this subsection is that:

(a) a national emergency declaration is in force; and

(b) either of the following apply:

(i) the exemption should be made so that the biologicals may be stockpiled to deal with a potential threat to public health that may be caused by the emergency to which the national emergency declaration relates;

(ii) the exemption should be made so that the biologicals can be made available urgently in Australia in order to deal with an actual threat to public health caused by the

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emergency to which the national emergency declaration relates; and

(c) the Minister is satisfied that the exemption is in the national interest.

Period of exemption

(3) An exemption under subsection (1) comes into force:

(a) on the day the exemption is made; or

(b) on a later day specified in the exemption.

(4) An exemption under subsection (1) remains in force for the period specified in the exemption, unless revoked earlier.

Note: Section 32CD deals with variation and revocation of the exemption.

Effect of inclusion of biological in the Register

(5) An exemption under subsection (1) ceases to have effect in relation to a particular biological when that biological becomes included in the Register under Division 4.

Exemption not a legislative instrument

(6) An exemption under subsection (1) is not a legislative instrument.

32CC Conditions of exemptions

An exemption under section 32CB is subject to conditions specified in the exemption about any of the following:

(a) the quantity of biologicals that are exempt;

(b) the source of those biologicals;

(c) the persons or class of persons who may import, export, manufacture or supply those biologicals;

(d) the supply of those biologicals (including the persons or class of persons to whom biologicals may be supplied for use and the circumstances under which a stockpile of biologicals may be supplied for use);

(e) the storage and security of those biologicals;

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(f) the keeping and disclosure of, and access to, records about those biologicals;
(g) the disposal of those biologicals;
(h) the manner in which any of those biologicals is to be dealt with if a condition of the exemption is breached;
(i) any other matters that the Minister thinks appropriate.

Whether or not biologicals are exempt under section 32CB is not affected by whether or not there is a breach of a condition under this section in relation to those biologicals.

Note 1: There are criminal offences and civil penalties related to the breach of a condition of an exemption: see sections 32CP and 32CQ.

Note 2: Section 32CD deals with variation and revocation of the conditions.

32CD Variation or revocation of exemption

Variation of exemption

(1) The Minister may, by writing, vary an exemption made under section 32CB by removing specified biologicals from the exemption.

Note: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Revocation of exemption

(2) The Minister may, by writing, revoke an exemption made under section 32CB.

Variation or revocation of conditions

(3) The Minister may, by writing:
(a) vary the conditions of an exemption made under section 32CB (including by imposing new conditions); or
(b) revoke the conditions of an exemption made under section 32CB.

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When variation or revocation takes effect

(4) A variation or revocation under this section takes effect:

(a) if the Minister states in the variation or revocation that the variation or revocation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day the variation or revocation is made; or

(b) in any other case—on a later day specified in the variation or revocation (which must not be earlier than 28 days after the day the variation or revocation is made).

32CE Informing persons of exemption etc.

If the Minister makes an exemption under section 32CB, the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph 32CC(c):

(a) the exemption;

(b) any variation or revocation of the exemption under section 32CD.

32CF Notification and tabling

Notification

(1) The Secretary must cause a notice setting out particulars of the following:

(a) an exemption made under section 32CB because of paragraph 32CB(2)(b) or subparagraph (2A)(b)(ii);

(b) a variation or revocation under section 32CD, to the extent that the variation or revocation relates to an exemption made under section 32CB because of paragraph 32CB(2)(b) or subparagraph (2A)(b)(ii);

to be published in the *Gazette* within 7 days after the day on which the exemption, variation or revocation is made. However, the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

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Tabling

(2) The Minister must cause a document setting out particulars of the following:

(a) an exemption made under section 32CB because of paragraph 32CB(2)(b) or subparagraph (2A)(b)(ii);

(b) a variation or revocation under section 32CD, to the extent that the variation or revocation relates to an exemption made under section 32CB because of paragraph 32CB(2)(b) or subparagraph (2A)(b)(ii);

to be tabled in each House of the Parliament within 5 sitting days of that House after the day on which the exemption, variation or revocation is made. However, the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

32CG Disposal of unused biologicals

(1) This section applies to a biological if:

(a) an exemption under section 32CB in relation to that biological ceases to have effect otherwise than because that biological becomes included in the Register under Division 4; and

(b) that biological has not been used before the exemption so ceases to have effect.

(2) The Secretary may arrange for the disposal of the biological in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which the biological is to be stored, supplied, destroyed, exported or otherwise disposed of.

(4) A method set out in the regulations under subsection (3) must not enable or permit any benefit to be conferred on a person (including the Commonwealth) other than the owner of the biological.

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32CJ Criminal offences and civil penalty for biologicals not conforming to standards etc.

(1) This section applies if:

(a) a biological is exempt under section 32CB; and

(b) a person supplies a batch of the biologicals; and

(c) the Secretary is satisfied that the biologicals included in that batch:

(i) do not conform to a standard applicable to the biologicals; or

(ii) are otherwise not fit to be used for their intended purposes.

(2) The Secretary may, by written notice given to the person, require the person to take steps to recall the biologicals included in that batch (except any of those biologicals that cannot be recalled because they have been administered to, or applied in the treatment of, a person).

(3) The notice may specify one or more of the following requirements:

(a) the steps to be taken to recall the biologicals;

(b) the manner in which the steps are to be taken;

(c) a reasonable period within which the steps are to be taken.

(4) The Secretary must, as soon as practicable after giving the notice, cause particulars of it to be published in the *Gazette* or on the Department's website.

Notice is not a legislative instrument

(5) A notice given under subsection (2) is not a legislative instrument. *Offences*

(6) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

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(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement; and

(d) either:

(i) the use of any of the biologicals has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of any of the biologicals, if any of the biologicals were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person failed to comply with that requirement.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(7) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(9) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

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Note: For strict liability, see section 6.1 of the *Criminal Code*.

Civil penalty

(11) A person contravenes this subsection if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person does not comply with the requirement.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Saving of other laws

(12) This section is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

Subdivision D—Exempting biologicals for certain uses

32CK Approvals for importing, exporting or supplying a biological for special and experimental uses

(1) The Secretary may, by notice in writing, grant an approval to a person for one or more of the following:

(a) the importation into Australia of a specified biological;

(b) the exportation from Australia of a specified biological;

(c) the supply in Australia of a specified biological;

that is:

(d) for use in the treatment of another person; or

(e) for use solely for experimental purposes in humans.

Note: For variation of an approval for use of the kind referred to in paragraph (1)(e), see subsection (9A).

(1A) An approval for use of the kind referred to in paragraph (1)(d) must not be granted to a person unless the person is a health practitioner.

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(2) Subsection (1) does not apply if the biological is included in the Register, the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2).

Application for approval

(3) An application for an approval for use of the kind referred to in paragraph (1)(d) must:

(a) be made to the Secretary; and

(aa) be in a form (if any) approved, in writing, by the Secretary; and

(b) be accompanied by such information relating to the biological the subject of the application as is required by the Secretary.

(4) An application for an approval for use of the kind referred to in paragraph (1)(e) must:

(a) be made to the Secretary; and

(b) be in a form (if any) approved, in writing, by the Secretary; and

(c) be accompanied by such information relating to the biological the subject of the application as is required by the Secretary; and

(d) be accompanied by the prescribed evaluation fee.

Secretary's decision

(5) If an application for an approval is made, the Secretary must:

(a) after having considered the application; and

(b) in the case of an application for an approval for use of the kind referred to in paragraph (1)(e)—after having evaluated the information submitted with the application;

notify the applicant of the decision on the application as soon as practicable after making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

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Conditions

(6) The Secretary may grant an approval under subsection (1) subject to any conditions that are specified in the notice of approval.

Note: There are criminal offences and a civil penalty related to the breach of a condition of an approval: see sections 32CP and 32CQ.

(7) Those conditions may include a condition relating to the charges that may be made for the biological to which the approval relates. This subsection does not limit subsection (6).

(8) An approval under subsection (1) for use of the kind referred to in paragraph (1)(e) is subject to the conditions (if any) specified in the regulations. Those conditions (if any) are in addition to any conditions imposed under subsection (6).

Note: There are criminal offences and a civil penalty related to the breach of a condition of an approval: see sections 32CP and 32CQ.

Varying approval for use solely for experimental purposes in humans

(9A) If:

(a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(e); and

(b) the person requests the Secretary to do either or both of the following:

(i) vary the biological specified in the approval;

(ii) vary the conditions imposed under subsection (6) on the approval; and

(c) the request is in a form (if any) approved, in writing, by the Secretary; and

(d) the request is accompanied by such information relating to the biological as is required by the Secretary; and

(e) the request is accompanied by the fee prescribed by the regulations;

the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation

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requested and may involve imposing new conditions on the approval or varying or removing existing conditions.

(9B) The Secretary must notify the person making the request under subsection (9A) of:

(a) the Secretary's decision on the request; and

(b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.

(9C) A variation under subsection (9A) takes effect at the time the Secretary notifies the person under subsection (9B) of the variation.

Approval not a legislative instrument

(10) An approval under subsection (1) is not a legislative instrument.

32CL Conditions of use of biological for experimental purposes in humans

The use by a person (the ***experimenter***) for experimental purposes in humans of a biological that is the subject of an approval:

(a) that is held by another person under subsection 32CK(1); and

(b) that covers the importation into Australia, or the supply in Australia, of the biological for use solely for experimental purposes in humans;

is subject to the conditions (if any) specified in the regulations relating to one or more of the following:

(c) the preconditions on the use of the biological for those purposes;

(d) the principles to be followed in the use of the biological for those purposes;

(e) the monitoring of the use, and the results of the use, of the biological for those purposes;

(f) the circumstances in which the experimenter must cease the use of the biological for those purposes.

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Note: There are criminal offences and a civil penalty related to the breach of
a condition applicable under regulations made for the purposes of this section: see sections 32CP and 32CQ.

32CM Authorities for health practitioners

(1) The Secretary may, in writing, authorise a specified medical practitioner to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in the authority.

Note: Section 32CN contains criminal offences relating to the giving an authority to a medical practitioner.

(1A) An application for an authority under subsection (1) must be in a form (if any) approved, in writing, by the Secretary.

(2) The Secretary may give an authority under subsection (1) subject to any conditions that are specified in the authority.

Note: There are criminal offences and a civil penalty related to the breach of
a condition of an authority: see sections 32CP and 32CQ.

(3) The Secretary may impose conditions (or further conditions) on an authority given to a person under subsection (1) by giving to the person written notice of the conditions (or further conditions).

Note: There are criminal offences and a civil penalty related to the breach of
a condition of an authority: see sections 32CP and 32CQ.

(4) An authority under subsection (1) may only be given to a medical practitioner:

(a) who is included in a class of medical practitioners prescribed by the regulations for the purposes of this paragraph; and

(b) who has the approval of an ethics committee to supply the specified biological.

Paragraph (b) does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection.

(5) An authority under subsection (1) may only be given in relation to a class or classes of recipients prescribed by the regulations for the purposes of this subsection.

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(6) The regulations may prescribe the circumstances in which a biological may be supplied under an authority under subsection (1).

(7) An authority under subsection (1) is not a legislative instrument.

(7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in those rules, so long as:

(a) the biological is supplied in the circumstances specified in those rules; and

(b) the conditions (if any) specified in those rules are satisfied.

(7B) In making rules under subsection (7A), the Minister must comply with:

(a) such requirements (if any) as are prescribed by the regulations; and

(b) such restrictions (if any) as are prescribed by the regulations; and

(c) such limitations (if any) as are prescribed by the regulations.

(7C) If:

(a) a person is authorised, by subsection (7A) rules, to supply a biological; and

(b) the person supplies the biological in accordance with those rules;

the person must:

(c) notify the supply to the Secretary; and

(d) do so within 28 days after the supply.

(7D) A notification under subsection (7C) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain such information as is prescribed by the regulations.

(7E) An approval of a form may require or permit information to be given in accordance with specified software requirements:

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(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

(7F) A person commits an offence if:
(a) the person is subject to a requirement under subsection (7C); and
(b) the person omits to do an act; and
(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(7G) An offence against subsection (7F) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of a biological if a health practitioner, on behalf of the person, does the following:
(a) notifies the supply to the Secretary within 28 days after the supply;
(b) makes the notification in accordance with the requirements referred to in subsection (7D).

Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

(7H) In recommending to the Governor-General that regulations should be made for the purposes of paragraph (7D)(b), the Minister must have regard to the principle that information should only be prescribed for the purposes of that paragraph if the information is reasonably required for the responsible scrutiny by the Secretary of the operation of the scheme embodied in subsection (7A).

32CN Criminal offences relating to the giving of an authority to a health practitioner

(1) A person commits an offence if:
(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and
(b) the person supplies the biological; and

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(c) either of the following applies:
(i) the supply is not in accordance with the authority;
(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6); and
(d) either:
(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person; and
(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:
(i) the supply is not in accordance with the authority; or
(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(4) A person commits an offence if:
(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and
(b) the person supplies the biological; and
(c) either of the following applies:
(i) the supply is not in accordance with the authority;
(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: 500 penalty units.

(4A) A person commits an offence if:
(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and
(b) the person supplies the biological; and
(c) either of the following applies:

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(i) the supply is not in accordance with the authority;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

(5) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and

(c) the person supplies a biological specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

(e) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person; and

(f) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:

(i) the supply is not in accordance with those rules; or

(ii) the supply is not in the circumstances specified in those rules; or

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(7) A person commits an offence if:

(a) the person is a health practitioner; and

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(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and

(c) the person supplies a biological specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 500 penalty units.

(8) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and

(c) the person supplies a biological specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(9) An offence against subsection (8) is an offence of strict liability.

Subdivision E—Exempting biologicals where substitutes are unavailable etc.

32CO Approvals where substitutes for biologicals are unavailable etc.

(1) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified biological; or

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(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

(c) therapeutic goods included in the Register that could act as a substitute for the biological:

(i) are unavailable or are in short supply; or

(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

(d) any of the following conditions is satisfied:

(i) the biological that is the subject of the application for approval is registered or approved for general marketing in at least one foreign country specified by the Secretary under subsection (5);

(ii) an application that complies with section 32DA has been made for inclusion of the biological in the Register;

(iii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

(e) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

(1A) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified biological; or

(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

(c) therapeutic goods included in the Register that could act as a substitute for the biological:

(i) are unavailable or are in short supply; or

(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

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(d) either:

(i) the biological that is the subject of the application for approval is not registered or approved for general marketing in any of the foreign countries specified by the Secretary under subsection (5); or

(ii) the biological that is the subject of the application for approval is registered or approved for general marketing in at least one foreign country specified by the Secretary under subsection (5), but is not readily available for importation into, and supply in, Australia; and

(e) the biological is registered or approved for general marketing in a foreign country; and

(f) the manufacturing and quality control procedures used in the manufacture of the biological are acceptable; and

(g) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(h) the approval is necessary in the interests of public health.

(2) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified biological; or

(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

(c) there are no therapeutic goods that are included in the Register that could act as a substitute for the biological; and

(d) either:

(i) an application that complies with section 32DA has been made for inclusion of the biological in the Register; or

(ii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

(e) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

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Application for approval

(3) An application for an approval must:

(a) be made to the Secretary; and

(b) be accompanied by such information relating to the biological as is required by the Secretary.

Secretary's decision

(4) If an application for an approval is made, the Secretary must, after having considered the application, notify the applicant of the decision on the application as soon as practicable after making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

Determinations

(5) The Secretary may, by legislative instrument, make a determination specifying foreign countries for the purposes of subparagraph (1)(d)(i).

(6) The Secretary may, by legislative instrument, make a determination specifying the kinds of biologicals that can be the subject of an approval under this section.

Conditions

(7) The Secretary may grant an approval subject to any conditions that are specified in the notice of approval.

Note: There are criminal offences and a civil penalty related to the breach of a condition of an approval under subsection (1), (1A) or (2): see sections 32CP and 32CQ.

Period of approval

(9) The Secretary may grant an approval for such period as is specified in the notice of approval.

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When approval lapses

(10) The approval lapses if:

(a) the period specified in the notice of approval expires; or

(b) a decision has been made on an application that has been made for inclusion of the biological in the Register.

(11) The approval lapses if:

(a) the Secretary is satisfied that paragraph (1)(c), (d), (e) or (f), paragraph (1A)(c), (d), (e), (f), (g) or (h), or paragraph (2)(c), (d), (e) or (f), as the case requires, no longer applies in relation to the biological, or that a condition of the approval has been contravened; and

(b) the Secretary has given to the person to whom the approval was granted a notice stating that the Secretary is so satisfied.

(12) The lapsing of the approval on the expiry of the period specified in the notice of approval does not prevent another approval being granted under this section in relation to the biological before that lapsing. The other approval may be expressed to take effect on the expiry of that period.

Approval not a legislative instrument

(13) An approval under subsection (1), (1A) or (2) is not a legislative instrument.

Subdivision F—Offences and civil penalties relating to breaching conditions of exemptions, approvals or authorities

32CP Offences for breaching a condition of an exemption, approval or authority

(1) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

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(i) a condition of an exemption applicable under regulations made for the purposes of subsection 32CA(3); or
(ii) a condition of an exemption under section 32CB; or
(iii) a condition of an approval under section 32CK; or
(iv) a condition applicable under regulations made for the purposes of section 32CL; or
(v) a condition of an authority under section 32CM; or
(vi) a condition of an approval under subsection 32CO(1), (1A) or (2); and

(c) the act or omission:
(i) except for a breach of a condition referred to in subparagraph (b)(ii)—has resulted in, will result in, or is likely to result in harm or injury to any person; or
(ii) for a breach of a condition referred to in subparagraph (b)(ii)—has caused, will cause, or is likely to cause a serious risk to public health.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches:
(i) a condition of an exemption applicable under regulations made for the purposes of subsection 32CA(3); or
(ii) a condition of an exemption under section 32CB; or
(iii) a condition of an approval under section 32CK; or
(iv) a condition applicable under regulations made for the purposes of section 32CL; or
(v) a condition of an authority under section 32CM; or

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(vi) a condition of an approval under subsection 32CO(1), (1A) or (2).

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence of strict liability if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 32CA(3); or

(ii) a condition of an exemption under section 32CB; or

(iii) a condition of an approval under section 32CK; or

(iv) a condition applicable under regulations made for the purposes of section 32CL; or

(v) a condition of an authority under section 32CM; or

(vi) a condition of an approval under subsection 32CO(1), (1A) or (2).

Penalty: 100 penalty units.

32CQ Civil penalty for breaching a condition of an exemption, approval or authority

A person contravenes this section if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 32CA(3); or

(ii) a condition of an exemption under section 32CB; or

(iii) a condition of an approval under section 32CK; or

(iv) a condition applicable under regulations made for the purposes of section 32CL; or

(v) a condition of an authority under section 32CM; or

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(vi) a condition of an approval under subsection 32CO(1), (1A) or (2).

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 4—Including biologicals in the Register

Subdivision A—Preliminary

32D Simplified outline of this Division

A Class 1 biological can be included in the Register if a proper application is made and the applicant certifies various matters (see Subdivision B).

An export only biological can be included in the Register if a proper application is made, the applicant certifies various matters and, if steps in the manufacture of the biological have been carried out outside Australia, the Secretary has certified (where appropriate) that the manufacturing and quality control procedures used in those steps are acceptable (see Subdivision BA).

A biological, other than a Class 1 biological or an export only biological, can be included in the Register if a proper application is made and the Secretary is satisfied the biological is suitable for inclusion following an evaluation of the biological (see Subdivision C).

Subdivision B—Class 1 biologicals

32DA Application for inclusion in the Register

(1) A person may make an application to the Secretary to include a Class 1 biological in the Register.

(2) An application must:

(a) be made in accordance with a form that is approved, in writing, by the Secretary; and

(b) be accompanied by a statement certifying the matters mentioned in subsection (3); and

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(c) be delivered to an office of the Department specified in the form; and
(d) be accompanied by the prescribed application fee.

(3) The applicant must certify that:
(a) the biological is a Class 1 biological; and
(b) the biological is safe for the purposes for which it is to be used; and
(c) the biological conforms to every standard (if any) applicable to it; and
(d) both of the following are complied with in relation to the biological:
(i) the applicable provisions of the Therapeutic Goods Advertising Code;
(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and
(e) the biological complies with all prescribed quality or safety criteria that are applicable to it; and
(f) the biological does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and
(g) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3):
(i) if those prohibitions cover imports—any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
(ii) if those prohibitions cover exports—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
(iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
(h) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions:
(i) if those prohibitions cover imports—any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

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(ii) if those prohibitions cover exports—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those conditions.

(4) An approval of a form may require or permit an application to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

32DB Inclusion of Class 1 biological in the Register

(1) If an application is made in accordance with section 32DA for a Class 1 biological to be included in the Register in relation to a person, the Secretary must include the biological in the Register in relation to the person.

Biological number

(2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.

(4) The certificate must:

(a) specify the biological number of the biological; and

(b) specify the day on which the inclusion of the biological in the Register commences.

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Duration of inclusion in the Register

(5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DC Refusal to include Class 1 biological in the Register

If:

(a) an application is made under subsection 32DA(1) to include a Class 1 biological in the Register; and

(b) the Secretary refuses the application;

the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

Subdivision BA—Export only biologicals

32DCA Application for inclusion in the Register

Application

(1) A person may make an application to the Secretary to include an export only biological in the Register.

(2) The application must:

(a) be made in accordance with a form that is approved, in writing, by the Secretary; and

(b) be accompanied by a statement made by the applicant certifying the matters mentioned in subsection (4); and

(c) be accompanied by the fee prescribed by regulations made for the purposes of this paragraph.

(3) An approval of a form may require or permit an application to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

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Certification of matters

(4) The matters the applicant must certify are:

(a) that the biological is an export only biological; and

(b) that the biological is safe for the purposes for which it is to be used; and

(c) that the presentation of the biological is not unacceptable; and

(d) that the biological conforms to every standard (if any) applicable to it; and

(e) that the requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations are complied with in relation to the biological; and

(f) that the biological complies with all prescribed quality or safety criteria that are applicable to it; and

(g) that all the manufacturers of the biological are nominated as manufacturers in the application; and

(h) if a step in the manufacture of the biological has been carried out in Australia—that the biological is exempt from the operation of Part 3-3 or that the step has been carried out by a person who:

(i) is the holder of a licence to carry out that step; or

(ii) is exempt from the operation of that Part in relation to that step; and

(i) that the biological does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(j) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3):

(i) if those prohibitions cover imports—that any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

(ii) if those prohibitions cover exports—that any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

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(k) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions:

(i) if those prohibitions cover imports—that any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

(ii) if those prohibitions cover exports—that any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

(l) any other matter prescribed by regulations made for the purposes of this paragraph.

Manufacturing steps outside Australia

(5) Subject to subsection (7), if one or more steps in the manufacture of the biological have been carried out outside Australia, the Secretary must certify, or refuse to certify, that the manufacturing and quality control procedures used in each such step are acceptable.

Note: See also subsections 32EA(5), (7A) and (7B) and section 32EB in relation to conditions and certifications for the manufacture of a biological outside Australia after the biological is included in the Register.

(6) In deciding whether so to certify for the purposes of subsection (5), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the biological has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the biological; or

(ii) if a step in the manufacture of the biological has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the biological; or

(iii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the

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manufacture of the biological is of an acceptable standard; and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the biological to be necessary:

(i) funds for the carrying out of that inspection by, or on behalf of, the Secretary; and

(ii) evidence that the manufacturer has agreed to such an inspection; and

(c) whether the applicant has complied with any requirements made by the Secretary under section 32JA in relation to the manufacture of the biological.

(7) If:

(a) one or more steps in the manufacture of the biological have been carried out outside Australia; and

(b) had the biological been manufactured in Australia, it would have been exempt from the operation of Part 3-3 because of the operation of subsection 34(1);

subsection (5) of this section does not apply in relation to those steps.

32DCB Inclusion of export only biological in the Register

Secretary must include biological in Register

(1) The Secretary must include an export only biological in the Register in relation to a person if:

(a) an application is made under subsection 32DCA(1) for the biological to be included in the Register in relation to the person; and

(b) the application complies with subsection 32DCA(2); and

(c) if one or more steps in the manufacture of the biological have been carried out outside Australia and the Secretary is required to make a decision under subsection 32DCA(5)— the Secretary has certified, under that subsection, that the

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manufacturing and quality control procedures used in each such step are acceptable.

Biological number

(2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.

(4) The certificate must:

(a) specify the biological number of the biological; and

(b) specify the day on which the inclusion of the biological in the Register commences.

Duration of inclusion in the Register

(5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DCC Refusal to include export only biological in the Register

If:

(a) a person makes an application under subsection 32DCA(1) to include an export only biological in the Register; and

(b) the Secretary refuses the application;

the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

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Subdivision C—Biologicals other than Class 1 biologicals or export only biologicals

32DD Application for inclusion in the Register

A person may make an application to the Secretary to include a biological, other than a Class 1 biological or an export only biological, in the Register.

32DDA Preliminary assessment of applications

(1) If an application is made under section 32DD for the inclusion of a biological in the Register, the Secretary must carry out an assessment of whether the requirements set out in subsection (2) of this section have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that class of biological; or

(ii) in such other manner as is approved, in writing, by the Secretary for that class of biological;

(b) the prescribed application fee for that class of biological must be paid;

(c) the application must be delivered to an office of the Department specified by the Secretary;

(d) the application must be accompanied by information that is:

(i) of a kind determined under subsection (9) for that class of biological; and

(ii) in a form determined under subsection (10) for that class of biological;

(e) if the Secretary so requires—the applicant must:

(i) deliver to the Department a reasonable number of samples of the biological; and

(ii) do so in a manner approved, in writing, by the Secretary;

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(f) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application must be accompanied by a statement from the applicant certifying that:

(i) if those prohibitions cover imports—any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

(ii) if those prohibitions cover exports—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

(g) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application must be accompanied by a statement from the applicant certifying that:

(i) if those prohibitions cover imports—any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

(ii) if those prohibitions cover exports—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

(iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those conditions.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

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(4) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(5) Subsection (4) does not apply if the period within which the Secretary must, under section 32DE, evaluate the biological to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of different forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and manners for making applications for different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

(8) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

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32DE Evaluation of biologicals

(1) If an application is made under section 32DD for a biological to be included in the Register in relation to a person, and the application has passed preliminary assessment, the Secretary must evaluate the biological for inclusion in the Register, having regard to:

(a) whether the quality, safety and efficacy of the biological for the purposes for which it is to be used have been satisfactorily established; and

(b) whether the presentation of the biological is acceptable; and

(c) whether the biological conforms to any standard applicable to it; and

(d) whether:

(i) the applicable provisions of the Therapeutic Goods Advertising Code; and

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or the regulations;

are complied with in relation to the biological; and

(e) if a step in the manufacture of the biological has been carried out outside Australia and the biological is not exempt from the operation of Part 3-3—whether the manufacturing and quality control procedures used in the step are acceptable; and

(f) if a step in the manufacture of the biological has been carried out in Australia, the biological is not exempt from the operation of Part 3-3 and the person is not exempt from the operation of that Part in relation to that step—whether that step has been carried out in accordance with that Part; and

(fa) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether, if the Secretary were to include the biological in the Register, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the biological would contravene those prohibitions; and

(fb) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—

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whether, if the Secretary were to include the biological in the Register, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the biological would contravene those conditions; and

(g) whether the biological contains substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(h) whether all of the manufacturers of the biological are nominated as manufacturers of the biological in the application; and

(i) such other matters (if any) as the Secretary considers relevant.

(2) For the purposes of paragraph (1)(e), subsections 25(2), (2E), (2F) and (2G) apply in a way corresponding to the way in which they apply for the purposes of paragraph 25(1)(g).

32DEA Biologicals (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make biologicals (priority applicant) determinations.

(2) A ***biologicals (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 32DD application that may be made by the person for the inclusion in the Register of a biological specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for biologicals (priority applicant) determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application;

(e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary

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specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a biologicals (priority applicant) determination;

(b) the consequences of the revocation of a biologicals (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) A period prescribed under paragraph 63(2)(daa) for the evaluation of a biological covered by a section 32DD application for which the applicant is a priority applicant may be shorter than the period prescribed under that paragraph for the evaluation of a biological covered by a section 32DD application for which the applicant is not a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 32DD application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(9) If a biologicals (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A biologicals (priority applicant) determination made under the regulations is not a legislative instrument.

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(11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of a person in a biologicals (priority applicant) determination.

Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with specification by class.

32DF Inclusion of biological in the Register

(1) If:

(a) an application is made under section 32DD for a biological to be included in the Register in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides that it is appropriate to include the biological in the Register after an evaluation under section 32DE; and

(c) no part of an evaluation fee under section 32DI that is due and payable by the person remains unpaid;

the Secretary must include the biological in the Register in relation to the person.

Biological number

(2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.

(4) The certificate must:

(a) specify the biological number of the biological; and

(b) specify the day on which the inclusion of the biological in the Register commences.

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Duration of inclusion in the Register

(5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DG Refusal to include biological in the Register

If:

(a) an application is made under section 32DD to include a biological in the Register; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary refuses the application;

the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

32DH Lapsing of application

(1) An application under section 32DD for inclusion of a biological in the Register lapses if:

(a) any part of the evaluation fee payable in respect of the biological remains unpaid at the end of the period of 42 days after the day on which the part became due and payable; or

(b) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 32JA, is false or misleading in a material particular; or

(c) the applicant fails to comply with a requirement under section 32JA to give information consisting of patient data in relation to the biological.

(2) In this section:

patient data, in relation to a biological, means information, derived from clinical trials, relating to individuals before, during and after

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the administration of the biological to those individuals, including, but not limited to, demographic, biochemical and haematological information.

32DI Evaluation fee

(1) If an application is made under section 32DD for a biological to be included in the Register, and the application has passed preliminary assessment, an evaluation fee specified in, or determined in accordance with, the regulations is payable by the applicant in respect of the evaluation of the biological for inclusion in the Register.

(2) The Secretary must notify the applicant in writing of the amount of the evaluation fee.

32DJ When evaluation fee due for payment

(1) Subject to sections 32DK and 32DM, an evaluation fee payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

(2) The evaluation fee is payable in the manner prescribed by the regulations.

32DK Payment of evaluation fee by instalments

(1) The regulations may provide for the payment of an evaluation fee to be made by such instalments and at such times as are ascertained in accordance with the regulations, and the evaluation fee is due and payable accordingly.

(2) Regulations made for the purposes of subsection (1) may provide that a person is not allowed to pay an evaluation fee by instalments if any part of an instalment of that or any other evaluation fee payable by the person was unpaid immediately after the time when it became due for payment.

(3) If:

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(a) the regulations make provision as mentioned in subsection (2); and

(b) an instalment of an evaluation fee under section 32DI was unpaid immediately after the time when it became due for payment;

the balance of the evaluation fee becomes due and payable immediately.

(4) Subsection (2) does not limit subsection (1).

32DL Recovery of evaluation fee

An evaluation fee may be recovered by the Commonwealth as a debt due to the Commonwealth.

32DM Reduction of evaluation fee where evaluation not completed within prescribed period

(1) Nothing in section 32DI, 32DJ or 32DK requires the applicant to pay more than $^{3}/_{4}$ of the evaluation fee before the completion of the evaluation if a period is prescribed under paragraph 63(2)(daa) for completing the evaluation.

(2) The Secretary must notify the applicant in writing of the day the evaluation is completed.

(3) If the evaluation is not completed within that period, the evaluation fee is $^{3}/_{4}$ of the fee that, apart from this subsection, would have been the evaluation fee.

(4) If:

(a) the evaluation is completed within that period; and

(b) part of the evaluation fee under section 32DI is unpaid when the evaluation is completed;

that part becomes due and payable on the completion of the evaluation.

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(5) For the purposes of this section, if a copy of the evaluation report, or a summary of that report, is given to either or both of the following:

(a) the applicant;

(b) a committee established under the regulations to advise the Secretary on applications to include biologicals in the Register where a period for evaluating the biologicals is prescribed under paragraph 63(2)(daa);

then the evaluation is taken to be completed immediately before the first copy or summary is so given.

Note: This subsection has the effect that if the applicant withdraws the application after being given a copy of the evaluation report, or a summary of that report, before the end of that period, the full evaluation fee is due and payable by the applicant.

(6) A notification under subsection (2) is not a legislative instrument.

Subdivision D—Transitional provisions for existing biologicals

32DN Transitional provisions for existing biologicals

Biologicals currently included in the Register

(1) If, immediately before the commencement of this section, therapeutic goods that are a biological were included in relation to a person:

(a) in the part of the Register for goods known as registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(c) in the part of the Register for medical devices included in the Register under Chapter 4;

then, as soon as practicable after the commencement of this section, the Secretary must:

(d) by writing, cancel the inclusion of the goods in that part; and

(e) include the biological in the Register under this Part in relation to the person; and

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(f) vary the Register as a result of that cancellation and inclusion.

Pending applications

(2) If:

(a) before the commencement of this section, an application was made for the registration or listing of therapeutic goods that are a biological or for the inclusion of such goods in the Register under Chapter 4; and

(b) immediately before that commencement, the application was not finally determined; and

(c) the application has not been, and is not, withdrawn either before or after that commencement; and

(d) the application is successful when it is finally determined; and

(e) the goods are included:

(i) in the part of the Register for goods known as registered goods; or

(ii) in the part of the Register for goods known as listed goods; or

(iii) in the part of the Register for medical devices included in the Register under Chapter 4;

then, as soon as practicable after that inclusion, the Secretary must:

(f) by writing, cancel the inclusion of the goods in that part; and

(g) include the biological in the Register under this Part in relation to the person; and

(h) vary the Register as a result of that cancellation and inclusion.

(3) For the purposes of this section, an application is ***finally determined*** when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

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Notice of decisions

(4) The Secretary must give the person written notice of the cancellation and inclusion under subsection (1) or (2). *Biological number*

(5) If the Secretary includes the biological in the Register under subsection (1) or (2), the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(6) As soon as practicable after the biological has been included in the Register under this Part, the Secretary must give to the person a certificate of the inclusion of the biological in the Register.

(7) The certificate must:

(a) specify the biological number of the biological; and

(b) specify the day on which the inclusion of the biological in the Register under this Part commences.

Duration of inclusion in the Register

(8) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

Annual charge

(9) If, during a financial year, the Secretary includes a biological in the Register under subsection (1) or (2), subsection 4(1AA) of the *Therapeutic Goods (Charges) Act 1989* does not apply in relation to the biological for that financial year.

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No review of decisions

(10) A decision under this section is taken not to be an initial decision for the purposes of section 60.

Subdivision E—Criminal offences and civil penalties

32DO Criminal offences for false statements in applications for including biologicals in the Register

(1) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and

(c) the statement is false or misleading in a material particular; and

(d) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and

(c) the statement is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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(5) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

32DP Civil penalty for false statements in applications for including biologicals in the Register

A person contravenes this section if the person in, or in connection with, an application for inclusion of a biological in the Register, makes a statement that is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

32DQ Criminal offence and civil penalty for failing to notify adverse effects etc. of biological while it is included in the Register

Criminal offence

(1) A person commits an offence if:

(a) a biological is included in the Register in relation to the person; and

(b) the person knows that particular information is information of a kind to which subsection (3) applies; and

(c) the person fails to give that information to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Civil penalty

(2) A person contravenes this subsection if:

(a) a biological is included in the Register in relation to the person; and

(b) the person knows that particular information is information of a kind to which subsection (3) applies; and

(c) the person fails to give that information to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

Relevant information

(3) This subsection applies to information of the following kinds:

(a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological);

(b) information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect;

(c) information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests.

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32DR Criminal offences and civil penalties for failing to notify adverse effects etc. of biological where application withdrawn or lapses

(1) If an application for inclusion of a biological in the Register is withdrawn or lapses, the Secretary may, within 14 days after the application is withdrawn or lapses, give the applicant written notice requiring the applicant:

(a) to inform the Secretary in writing whether the applicant is aware of any information of a kind to which subsection (2) applies; and

(b) if the applicant is aware of such information, to give the information to the Secretary in writing.

(2) This subsection applies to information of the following kinds:

(a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological);

(b) information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect;

(c) information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests.

Offences

(3) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (1); and

(b) the person fails to comply with the notice within 30 days after the notice is given to the person.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person gives information in purported compliance with a notice under subsection (1); and

(b) the information is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Civil penalties

(5) A person contravenes this subsection if:

(a) the Secretary gives a notice to the person under subsection (1); and

(b) the person fails to comply with the notice within 30 days after the notice is given to the person.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

(6) A person contravenes this subsection if:

(a) the person gives information in purported compliance with a notice under subsection (1); and

(b) the information is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

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Subdivision F—Advice from Gene Technology Regulator

32DS Consultation with Gene Technology Regulator

(1) This section applies to an application for inclusion of a biological in the Register if the biological is, or contains, a GM product or a genetically modified organism.

(2) Subject to subsection (5), the Secretary must give written notice to the Gene Technology Regulator:

(a) stating that the application has been made; and

(b) requesting the Gene Technology Regulator to give advice about the application.

(3) If the Secretary gives the Gene Technology Regulator a notice under subsection (2), the Gene Technology Regulator may give written advice to the Secretary about the application.

(4) The advice is to be given within the period specified in the notice.

(5) If an advice from the Gene Technology Regulator is in force under section 32DT in relation to a class of biologicals, the Secretary is not required to notify the Gene Technology Regulator under this section in relation to an application for inclusion in the Register of a biological belonging to that class.

(6) A notice under subsection (2) is not a legislative instrument.

32DT Secretary may seek advice about classes of GM products or genetically modified organisms

(1) The Secretary may request advice from the Gene Technology Regulator in relation to:

(a) biologicals that consist of, or that contain, a GM product belonging to a class of GM products specified in the request; or

(b) biologicals that consist of, or that contain, genetically modified organisms belonging to a class of genetically modified organisms specified in the request.

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(2) A request for advice under subsection (1) must specify the matters to which the advice is to relate.

(3) If the Secretary requests advice from the Gene Technology Regulator under subsection (1), the Gene Technology Regulator may provide written advice in relation to the matters specified in the request.

(4) If the Gene Technology Regulator gives advice to the Secretary under subsection (3), the advice remains in force until it is withdrawn by the Gene Technology Regulator by written notice given to the Secretary.

32DU Secretary to take advice into account

If the Secretary receives advice from the Gene Technology Regulator:

(a) in response to a notice under section 32DS within the period specified in the notice; or

(b) under section 32DT;

the Secretary must:

(c) ensure that the advice is taken into account in making a decision on the application to which the notice relates, or on an application to which the advice under section 32DT relates, as the case requires; and

(d) inform the Gene Technology Regulator of the decision on the application.

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Division 5—Conditions

32E What this Division is about

Inclusions of biologicals in the Register are subject to certain automatic conditions. The Minister and the Secretary may impose further conditions.

32EA Conditions applying automatically

Entry and inspection powers

(1) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will:

(a) allow an authorised person:

(i) to enter, at any reasonable time, any premises (including premises outside Australia) at which that person or any other person deals with the biological, complies with record-keeping conditions under paragraph 32EC(2)(c) or keeps documents that relate to the biological; and

(ii) while on those premises, to inspect those premises and any biological on those premises and to examine, take measurements of, conduct tests on or take samples of any biological on those premises or any thing on those premises that relates to any biological; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with a condition under paragraph 32EC(2)(c); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the biological; and

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(b) if requested to do so by an authorised person, produce to the person such documents relating to the biological included in the Register as the person requires and allow the person to copy the documents; and

(c) if requested to do so by an authorised person, make any record kept in compliance with a condition under paragraph 32EC(2)(c) available to the authorised person for inspection:

(i) if the authorised person requires the record to be made available immediately—immediately; and

(ii) if the authorised person requires the record to be made available at or before a time specified by the authorised person—at or before that time; and

(iii) in the form required by the authorised person.

(2) An authorised person is not authorised to enter premises as mentioned in subsection (1) unless the person has shown his or her identity card issued under section 52 if required by the occupier of the premises. For the purposes of this subsection, ***occupier***, in relation to premises, includes a person present at the premises who is in apparent control of the premises.

Delivery of samples

(3) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will deliver a reasonable number of samples of the biological if the Secretary so requests:

(a) within the period, of not less than 14 days after the day the request is made, specified in the request; and

(b) in accordance with any other requirements specified in the request.

Manufacturing

(4) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will:

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(a) if a manufacturer who was not nominated as a manufacturer of the biological in the application for inclusion of the biological in the Register is to become a manufacturer of a step in the manufacture of the biological—inform the Secretary in writing of that fact and of the name and address of that manufacturer before that manufacturer begins to carry out that step; and

(b) if premises that were not nominated in the application as premises to be used in the manufacture of the biological are to become premises used in a step in the manufacture of the biological—inform the Secretary in writing of that fact and of the name and address of the new premises before the premises are first so used.

(5) The inclusion of a biological, other than a Class 1 biological, in the Register is subject to a condition that:

(a) each step in the manufacture of the biological that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step or who is exempt from the operation of Part 3-3 in relation to that step; and

(b) each step in the manufacture of the biological that is carried out outside Australia is the subject of a certification in force under subsection 32EB(2).

(6) Subsection (5) does not apply if the biological is exempt from the operation of Part 3-3.

(7) Paragraph (5)(b) does not apply in relation to a step that was the subject of any evaluation under section 32DE. This subsection ceases to apply in relation to that step if either or both of the following occur:

(a) that step begins to be carried out at premises that are different from the premises in respect of which that evaluation was conducted;

(b) that step begins to be carried out by a manufacturer that is different from the manufacturer in respect of which that evaluation was conducted.

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(7A) Paragraph (5)(b) does not apply in relation to a step that:

(a) is the subject of a certification in force under subsection 32DCA(5); or

(b) was not required to be the subject of a decision under that subsection because of subsection 32DCA(7).

(7B) Paragraph (7A)(a) ceases to apply in relation to that step if either or both of the following occur:

(a) that step begins to be carried out at premises that are different from the premises in respect of which that certification was given;

(b) that step begins to be carried out by a manufacturer that is different from the manufacturer in respect of which that certification was given.

Expiry date

(8) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will not supply a batch of the biological in Australia, or export a batch of the biological from Australia, after the expiry date for the biological.

Advertising

(9) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will not, by any means, advertise the biological for an indication other than an indication accepted in relation to that inclusion.

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32EB Certification of manufacturing steps outside Australia

(1) The person in relation to whom a biological, other than a Class 1 biological, is included in the Register may apply to the Secretary for a certification under this section of a step in the manufacture of the biological that is to be carried out outside Australia.

(2) If an application is made to the Secretary under this section, the Secretary may, by writing, certify that the manufacturing and quality control procedures used in that step are acceptable. The Secretary must give the person written notice of the certification.

(3) In deciding whether to give the certification, subsections 25(2), (2E), (2F) and (2G) apply in a way corresponding to the way in which they apply for the purposes of paragraph 25(1)(g).

32EC Imposition of conditions by legislative instrument

(1) The inclusion of a biological in the Register is subject to the conditions set out in a determination under subsection (2).

(2) The Minister may, by legislative instrument, make a determination setting out conditions for the purposes of subsection (1), being conditions that relate to:

(a) the manufacture of the biological; or

(b) the custody, use, supply, disposal or destruction of the biological; or

(c) the keeping of records relating to the biological; or

(ca) reporting requirements relating to the biological; or

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the biological; or

(e) such other matters relating to the biological as the Minister thinks appropriate.

(3) Without limiting subsection (2), different conditions may be specified for different classes of biologicals.

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32ED Imposition of conditions at time biological included in the Register

(1) If the Secretary includes a biological in the Register in relation to a person, the Secretary may, by notice in writing given to the person, impose conditions on the inclusion of the biological in the Register.

(2) A notice under subsection (1) is not a legislative instrument.

32EE Imposition or variation or removal of conditions after biological included in the Register

(1) The Secretary may, by notice in writing given to the person in relation to whom a biological is included in the Register, impose new conditions on the inclusion or vary or remove conditions imposed under section 32ED or this subsection.

(2) The Secretary's power under subsection (1) may be exercised at the request of the person concerned or on the Secretary's own initiative. A request must be accompanied by the prescribed fee.

(3) The imposition or variation or removal of a condition under subsection (1) takes effect:

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(aa) in the case of an imposition or variation requested by the person, and to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day; or

(ab) in the case of a removal to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day; or

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(b) in any other case—on a later day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

(3A) For the purposes of paragraphs (3)(aa) and (ab), the earlier day must not be earlier than the day the notice is given to the person.

(4) A notice under subsection (1) is not a legislative instrument.

32EF Criminal offences for breach of condition

(1) A person commits an offence if:
(a) a biological is included in the Register in relation to the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the inclusion of the biological in the Register; and
(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:
(a) a biological is included in the Register in relation to the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the inclusion of the biological in the Register.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

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(a) a biological is included in the Register in relation to the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the inclusion of the biological in the Register.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

32EG Civil penalty for breach of condition

A person contravenes this section if:
(a) a biological is included in the Register in relation to the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the inclusion of the biological in the Register.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

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Division 6—Suspension from the Register

32F What this Division is about

The Secretary may suspend biologicals from the Register in certain circumstances. A biological that is suspended is taken not to be included in the Register for most purposes.

32FA Suspension of biological from the Register

(1) The Secretary may, by written notice given to a person in relation to whom a biological is included in the Register, suspend the biological from the Register if:

(a) the Secretary is satisfied that:

(i) there is a potential risk of death, serious illness or serious injury if the biological continues to be included in the Register; and

(ii) it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the biological would not cause a potential risk of death, serious illness or serious injury if the biological were to continue to be included in the Register; or

(b) the Secretary is satisfied that it is likely that there are grounds for cancelling the entry of the biological from the Register under Division 7 (other than because of paragraph 32GA(1)(a), (d) or (g)).

Notice of proposed suspension in some cases

(2) However, before suspending a biological from the Register because it is likely that there are grounds for cancelling the entry of the biological from the Register under section 32GC, the Secretary must:

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(a) inform the person by written notice that the Secretary proposes the suspension and set out the reasons for it; and

(b) invite the person to make written submissions to the Secretary in relation to the proposed suspension within the period specified in the notice (being not less than 28 days after the day the notice is given).

(3) The Secretary must not make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

Period of suspension

(4) A notice under subsection (1) must specify the period of the suspension (which must not exceed 6 months).

Note: Section 32FB deals with when the suspension takes effect and extensions of the suspension.

Publication

(5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the suspension.

Notice not a legislative instrument

(6) A notice under subsection (1) is not a legislative instrument.

32FB When suspension takes effect etc.

(1) A suspension under section 32FA takes effect:

(a) if the notice under subsection 32FA(1) states that the suspension is necessary to prevent a potential risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(b) in any other case—on a later day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

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(2) The suspension has effect until:
(a) the Secretary revokes it under section 32FC; or
(b) the end of:
(i) the period specified under subsection 32FA(4); or
(ii) if the period is extended under subsection (3) of this section—the period as so extended.

Extension of suspension

(3) The Secretary may, by written notice given to the person, extend the period specified under subsection 32FA(4) by a further specified period not exceeding 6 months.

Publication

(4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the extension.

Notice not a legislative instrument

(5) A notice under subsection (3) is not a legislative instrument.

32FC Revocation of suspension

(1) The Secretary must revoke a suspension under section 32FA, by written notice given to the person in relation to whom the biological is included in the Register, if the Secretary is satisfied that:
(a) the ground on which the biological was suspended from the Register no longer applies; and
(b) there are no other grounds for suspending the biological from the Register.

(2) The Secretary's power to revoke the suspension may be exercised:
(a) if the person in relation to whom the biological is included in the Register applies in writing to the Secretary; or

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(b) on the Secretary's own initiative.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

Notice of refusal to revoke suspension

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:
(a) notify the applicant in writing of his or her decision; and
(b) state in the notice the reasons for the decision.

Notice not a legislative instrument

(5) A notice under subsection (1) is not a legislative instrument.

32FD Effect of suspension

(1) If a biological is suspended from the Register under section 32FA, the biological is taken, for the purposes of this Act (other than section 32DQ, Division 5, sections 32FB and 32FC and Divisions 7 and 9), not to be included in the Register while the suspension has effect.

Note: Dealing in a biological that is not included in the Register may be a criminal offence or may contravene a civil penalty provision: see Division 2.

(2) While the suspension has effect, the Secretary's power under Division 7 to cancel the entry of the biological from the Register is not affected.

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Division 7—Cancellation from the Register

32G What this Division is about

The Secretary may cancel inclusions of biologicals in the Register in certain circumstances.

32GA Immediate cancellation of biological from the Register in various circumstances

(1) The Secretary may, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if:

(a) the Secretary is satisfied that there would be an imminent risk of death, serious illness or serious injury if the biological continued to be included in the Register; or

(b) the biological ceases to be a biological or the biological becomes covered by an order under section 7 declaring goods not to be therapeutic goods; or

(c) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or

(d) the person requests in writing the cancellation of the entry of the biological from the Register; or

(e) the biological contains substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(f) the Secretary is satisfied that a statement made in, or in connection with, the application for including the biological in the Register was false or misleading in a material particular; or

(g) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register is not paid within 28 days after it becomes payable; or

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(h) the person has failed to comply with a condition mentioned in subsection 32EA(1) or (3); or

(i) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the biological and the Secretary is satisfied that the contravention is significant; or

(j) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the biological and the Secretary is satisfied that the contravention is significant; or

(k) there is a breach, involving the biological, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of the biological is misleading to a significant extent.

(1AA) Paragraph (1)(k) does not apply to export only biologicals.

(1A) The Secretary must, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if the Secretary is satisfied that:

(a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the biological would contravene one or more of those prohibitions; or

(b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions— imports into Australia, exports from Australia or supplies in Australia of the biological would contravene one or more of those conditions.

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(2) A notice under subsection (1) or (1A) is not a legislative instrument.

32GB Immediate cancellation of biological from the Register after failure to comply with information gathering notice

(1) The Secretary may, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if:

(a) the Secretary gives to the person a notice under section 32JA requiring the person to give to the Secretary information, or to produce to the Secretary documents, relating to the biological; and

(b) the notice under section 32JA is given for the purposes of ascertaining whether any of the certifications by the person under subsection 32DA(3) or 32DCA(4) in relation to the biological are incorrect; and

(c) the person fails to comply with the notice under section 32JA within a further 14 days after the end of the period specified in that notice.

(2) The Secretary may, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if:

(a) the Secretary gives to the person a notice under section 32JA requiring the person to give to the Secretary information, or to produce to the Secretary documents, relating to whether the biological is being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia; and

(b) either:

(i) the information or documents given are to the effect that the biological is not being supplied in Australia, imported into Australia or exported from Australia; or

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(ii) the person fails to comply with the notice under section 32JA within a further 14 days after the end of the period specified in that notice.

(3) A notice under subsection (1) or (2) is not a legislative instrument.

32GC Cancellation of biological from the Register after notice of proposed cancellation

(1) The Secretary may, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if:

(a) it appears to the Secretary that the quality, safety or efficacy of the biological is unacceptable or that the presentation of the biological is not acceptable; or

(b) the biological has changed so that it has become separate and distinct from the biological as so included; or

Note: Section 32AB deals with when a biological is separate and distinct from other biologicals.

(c) the person has failed to comply with a condition to which the inclusion of the biological is subject (except a condition mentioned in subsection 32EA(1) or (3)); or

(d) the Secretary gives to the person a notice under section 32JA:

(i) that requires the person to give to the Secretary information, or to produce to the Secretary documents, relating to the biological; and

(ii) in respect of which section 32GB does not apply;

and the person fails to comply with that notice within a further 14 days after the end of the period specified in that notice; or

(e) the person contravenes subsection 32DQ(1) or (2) in relation to the biological; or

(f) the biological does not conform to a standard applicable to it; or

(fa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the biological; or

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(fb) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the biological; or

(g) either of the following has not been complied with in relation to the biological:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or under the regulations.

(2) However, before cancelling the entry of the biological from the Register, the Secretary must:

(a) inform the person in writing that the Secretary proposes the cancellation and set out the reasons for it; and

(b) invite the person to make written submissions to the Secretary in relation to the proposed cancellation within the period specified in the notice (being not less than 28 days after the day the notice is given).

(3) The Secretary must not make a decision relating to the proposed cancellation until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

(4) A notice under subsection (1) is not a legislative instrument.

32GD Revocation of cancellation of biological upon request

(1) If:

(a) the Secretary cancels the entry of a biological from the Register because of the request of a person made under paragraph 32GA(1)(d); and

(b) before the end of the period of 90 days beginning on the day the biological ceased to be included in the Register, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the request is accompanied by the prescribed application fee;

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the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

32GDA Revocation of cancellation of biological upon request— payment of annual charge

(1) If:

(a) the Secretary cancels the entry of a biological from the Register because the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register was not paid within 28 days after it becomes payable; and

(b) before the end of the period of 90 days beginning on the day the biological ceased to be included in the Register, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register has been paid; and

(d) the request is accompanied by the prescribed application fee;

the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

32GE Publication of cancellation of entry from Register

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after cancelling an entry of a biological from the Register, a notice setting out particulars of the cancellation.

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32GF Date of effect of cancellation of entries from Register

If the Secretary cancels an entry of a biological from the Register, the cancellation has effect on the day on which the notice of cancellation is given to the person in relation to whom the biological was included in the Register.

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Division 8—Public notification, and recall, of biologicals

32H What this Division is about

The Secretary may require a person to recall biologicals, or to inform the public about biologicals, that do not comply with requirements or cannot lawfully be supplied. There are criminal offences and a civil penalty for breaching such a requirement.

32HA Public notification, and recall, of biologicals

(1) The Secretary may, by notice in writing, impose requirements, relating to a biological, on a person if:

(a) any of the circumstances referred to in the 2nd column of an item in the following table occur in relation to the biological; and

(b) the person is referred to in the 3rd column of that item.

Circumstances in which requirements may be imposed

Item	Circumstance relating to biological	Person subject to requirements
1	It is supplied while it is included in the Register, but the Secretary is satisfied that it does not conform with a standard applicable to it	The person in relation to whom it is included in the Register
2	It is a biological, other than a Class 1 biological, and it is supplied while it is included in the Register, but the Secretary is satisfied that the manufacturing principles have not been observed in its manufacture	The person in relation to whom it is included in the Register

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to biological**	**Person subject to requirements**
3	It is supplied while: (a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or (b) it is exempt under section 32CB; or (c) it is the subject of an approval under subsection 32CK(1); or (d) it is the subject of an authority under subsection 32CM(1) or (7A); or (e) it is the subject of an approval under subsection 32CO(1), (1A) or (2); but the Secretary is satisfied that it does not conform with a standard applicable to it	The person supplying it
4	It is a biological, other than a Class 1 biological, and it is supplied while: (a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or (b) it is exempt under section 32CB; or (c) it is the subject of an approval under subsection 32CK(1); or (d) it is the subject of an authority under subsection 32CM(1) or (7A); or (e) it is the subject of an approval under subsection 32CO(1), (1A) or (2); but the Secretary is satisfied that the manufacturing principles have not been observed in its manufacture	The person supplying it
4A.	It is supplied and the Secretary is satisfied that: (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply contravenes one or more of those	The person supplying it

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Section 32HA

Circumstances in which requirements may be imposed

Item	Circumstance relating to biological	Person subject to requirements
	prohibitions; or (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions	
5	It is supplied while: (a) it is not included in the Register; and (b) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and (c) it is not exempt under section 32CB; and (d) it is not the subject of an approval under subsection 32CK(1); and (e) it is not the subject of an authority under subsection 32CM(1) or (7A); and (f) it is not the subject of an approval under subsection 32CO(1), (1A) or (2)	The person supplying it
6	It is supplied while it is exempt under section 32CB, and the Secretary is satisfied that it is not fit to be used for its intended purpose	The person supplying it
7	It is counterfeit goods (within the meaning of section 42E)	The person supplying it
8	It is a biological, other than a Class 1 biological, and it is supplied while it is included in the Register, but the Secretary is satisfied that there is a breach of the condition set out in subsection 32EA(5)	The person in relation to whom it is included in the Register
9	It appears to the Secretary that the quality, safety or efficacy of the biological is unacceptable or that the presentation of the biological is not acceptable	The person in relation to whom the biological is included in the Register
10	It has been suspended from the Register	The person in relation to whom it is included in the Register

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to biological**	**Person subject to requirements**
11	Its entry has been cancelled from the Register	The person in relation to whom it is included in the Register

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recall the biological that has been supplied;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the circumstances referred to in paragraph (1)(a) have occurred in relation to the biological;

(ba) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to either or both of the following:

(i) the biological;

(ii) the circumstances referred to in paragraph (1)(a);

(c) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or supply of the biological;

(d) to notify the Secretary, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to the persons to whom the biological has been supplied.

(3) If the circumstances referred to in paragraph (1)(a) apply only to a batch of the biological, the Secretary may limit the imposition of the requirements to that batch.

(4) A requirement to recall a biological under this section does not apply to a biological that cannot be recalled because it has been administered to, or applied in the treatment of, a person.

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(5) A notice under subsection (1) is not a legislative instrument.

32HB Publication of requirements

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after imposing a requirement under section 32HA, a notice setting out particulars of the requirement.

32HC Criminal offences for non-compliance with requirements

(1) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 32HA; and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 32HA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 32HA.

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Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

32HD Civil penalty for non-compliance with requirements

A person contravenes this section if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 32HA.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

32HE Powers of suspension and cancellation unaffected

Imposition of a requirement under section 32HA does not affect the Secretary's power to suspend a biological, or cancel the entry of a biological, from the Register under this Part.

32HF Saving of other laws

This Division is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

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Division 9—Obtaining information or documents

Subdivision A—Preliminary

32J What this Division is about

The Secretary may by written notice seek information or documents relating to:

- applications for inclusion of biologicals in the Register; or
- biologicals included in the Register; or
- the supply of, and other matters relating to, biologicals covered by exemptions under Division 3.

There are criminal offences for failing to comply with a notice and for giving false or misleading information or documents and civil penalties for giving false or misleading information or documents.

Subdivision B—Obtaining information or documents for biologicals included or proposed to be included in the Register

32JA Secretary may require information or documents

(1) The Secretary may, by written notice given to a person:

(a) who is an applicant for the inclusion of a biological in the Register; or

(b) in relation to whom a biological is included in the Register; or

(c) in relation to whom a biological was, at any time during the previous 5 years, included in the Register;

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require the person to give to the Secretary information, or to produce to the Secretary documents, that are relevant to one or more of the following:

(d) the formulation of the biological;

(e) the composition of the biological;

(f) the design specifications of the biological;

(g) the quality of the biological;

(h) the method and place of manufacture or preparation of the biological and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the biological;

(i) the presentation of the biological;

(j) the safety and efficacy of the biological for the purposes for which it is to be used;

(k) whether the biological conforms with a standard applicable to it;

(l) whether the biological complies with conditions (if any) on the inclusion of the biological in the Register;

(m) whether either of the following has not been complied with in relation to the biological:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or under the regulations;

(n) if the biological is included in the Register in relation to the person—whether the biological is being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(na) if the biological is included in the Register in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the biological contravene those prohibitions;

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(nb) if the biological is included in the Register in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia or any exports from Australia of the biological contravene those conditions;

(o) the regulatory history of the biological in another country;

(p) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

(2) The person must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) in the form specified in the notice.

Note: Section 32JB contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JC contains a civil penalty for giving false or misleading information or documents.

(3) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(4) If a notice is given under subsection (1) to a person covered by paragraph (1)(c), then paragraphs (1)(d) to (p) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the biological was included in the Register.

32JB Criminal offences for failing to comply with a notice etc.

(1) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(aa) the person is covered by paragraph 32JA(1)(b) or (c); and

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(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

Note: Failure to comply with the notice might also lead to suspension or cancellation of the entry of a biological in the Register (see Divisions 6 and 7).

(1A) Subsection (1) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1A): see subsection 13.3(3) of the *Criminal Code*.

(1B) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(b) the person is covered by paragraph 32JA(1)(b) or (c); and

(c) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1C) An offence against subsection (1B) is an offence of strict liability.

(1D) Subsection (1B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1D): see subsection 13.3(3) of the *Criminal Code*.

(2) A person commits an offence if:

(a) the person is given a notice under section 32JA in relation to a biological; and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular; and

(d) either:

(i) the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any person; or

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(ii) the use of the biological, if the biological were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (5) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(5) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(6) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

(7) An offence against subsection (6) is an offence of strict liability.

32JC Civil penalty for giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

(a) the person is given a notice under section 32JA; and

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(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

32JD Self-incrimination

(1) A person is not excused from giving information or producing a document under section 32JA on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; and

(b) giving the information or producing the document; and

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

(d) in criminal proceedings, except proceedings for an offence against subsection 32JB(1), (1B), (2), (5) or (6); or

(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 32JC.

Subdivision C—Obtaining information or documents for biologicals covered by exemptions

32JE Secretary may require information etc. about biologicals exempt under the regulations

(1) If a person is exempt under subsection 32CA(1) in relation to a biological, the Secretary may give the person a written notice requiring the person to give to the Secretary specified information,

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or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

(2) If a biological is exempt under subsection 32CA(2), the Secretary may give the sponsor of the biological a written notice requiring the sponsor to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(3) A person given a notice under subsection (1) or (2) must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

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(4) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

32JF Secretary may require information etc. about biologicals exempt to deal with emergencies

(1) This section applies to a person who is required to comply with a condition of an exemption of a biological under section 32CB.

(2) The Secretary may, by written notice given to the person, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

(3) The person must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

(4) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

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(b) by way of a specified kind of electronic transmission.

32JG Secretary may require information etc. about biologicals exempt for special and experimental uses

Approval under subsection 32CK(1)

(1) The Secretary may give to a person who is granted an approval under subsection 32CK(1) in relation to a biological a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Approval under subsection 32CK(1)—use by another person

(2) The Secretary may give to a person (the ***experimenter***) using a biological that is the subject of an approval:

(a) that is held by another person under subsection 32CK(1); and

(b) that covers the importation into Australia, or the supply in Australia, of the biological for use solely for experimental purposes in humans;

a written notice requiring the experimenter to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to either or both of the following:

(c) the use of the biological;

(d) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

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Authority under subsection 32CM(1)

(3) The Secretary may give to a person who is granted an authority under subsection 32CM(1) in relation to a biological a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Authority under subsection 32CM(7A) rules

(3A) If a person is authorised, by subsection 32CM(7A) rules, to supply a biological, the Secretary may give the person a written notice requiring the person to give the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(4) A person given a notice under subsection (1), (2), (3) or (3A) must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) in the form specified in the notice.

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Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

(5) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

32JH Secretary may require information etc. about biologicals exempt where substitutes are unavailable etc.

(1) The Secretary may give to a person who is granted an approval under subsection 32CO(1), (1A) or (2) in relation to a biological a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(2) A person given a notice under subsection (1) must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

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(3) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

32JI Criminal offences for failing to comply with a notice etc.

(1) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(1A) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(2) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(3) A person commits an offence if:

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(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

32JJ Civil penalty for giving false or misleading information or document in compliance with a notice

A person contravenes this section if:
(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

32JK Self-incrimination

(1) A person is not excused from giving information or producing a document under section 32JE, 32JF, 32JG or 32JH on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:
(a) the information given or the document produced; and
(b) giving the information or producing the document; and

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(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

(d) in criminal proceedings, except proceedings for an offence against subsection 32JI(1), (1A), (2) or (3); or

(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 32JJ.

Subdivision D—Inspecting, copying and retaining documents

32JL Secretary may inspect and copy documents

The Secretary may inspect a document produced under section 32JA, 32JE, 32JF, 32JG or 32JH and may make and retain copies of the whole or a part of the document.

32JM Secretary may retain documents

(1) The Secretary may take possession of a document produced under section 32JA, 32JE, 32JF, 32JG or 32JH, and retain it for as long as is reasonably necessary.

(2) The person otherwise entitled to possession of the document is entitled to be supplied, as soon as practicable, with a copy certified by the Secretary to be a true copy.

(3) The certified copy must be received in all courts and tribunals as evidence as if it were the original.

(4) Until a certified copy is supplied, the Secretary must provide the person otherwise entitled to possession of the document, or a person authorised by that person, reasonable access to the document for the purposes of inspecting and making copies of the whole or a part of the document.

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Part 3-3—Manufacturing of therapeutic goods

33A Part does not apply to a medical device

This Part does not apply to a medical device.

Note: Chapter 4 deals with medical devices.

33B Application of this Part to biologicals

This Part does not apply to a Class 1 biological.

34 Exempt goods and exempt persons

(1) The regulations may exempt therapeutic goods or a class of therapeutic goods identified in the regulations from the operation of this Part.

(2) The regulations may exempt a person identified in the regulations from the operation of this Part in relation to the manufacture or a step in the manufacture of therapeutic goods or a class of therapeutic goods identified in the regulations.

(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, as is specified in the regulations.

35 Criminal offences relating to manufacturing therapeutic goods

(1) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

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(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person carried out the step in the manufacture of the goods.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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(4A) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

(5) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises; and

(e) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(f) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person carried out the step in the manufacture of the goods.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

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Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (9) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(9) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(10) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

35A Civil penalties relating to manufacturing therapeutic goods

(1) A person contravenes this subsection if:

(a) the person carries out a step in the manufacture of therapeutic goods at premises in Australia; and

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(b) the goods are for supply for use in humans; and
(c) the goods are not exempt under section 18A or 32CB; and
(d) none of the following applies:
(i) the goods are exempt goods;
(ii) the person is an exempt person in relation to the manufacture of the goods;
(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

(2) A person contravenes this subsection if:
(a) the person carries out a step in the manufacture of therapeutic goods at premises in Australia; and
(b) the goods are for supply for use in humans; and
(c) the goods are exempt under section 18A or 32CB; and
(d) the person is not the holder of a licence that:
(i) is in force; and
(ii) authorises the carrying out of that step in relation to the goods at those premises.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

35B Criminal offences relating to breaching a condition of a licence

(1) A person commits an offence if:
(a) the person holds a licence; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the licence; and
(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

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Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(4) A person commits an offence if:

(a) the person holds a licence; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the licence.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person holds a licence; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the licence.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

35C Civil penalty relating to breaching a condition of a licence

A person contravenes this section if:

(a) the person holds a licence; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the licence.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

36 Manufacturing principles

(1) The Minister may, from time to time, determine written principles to be observed in the manufacture of therapeutic goods for use in humans.

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(2) The manufacturing principles may relate to:

(a) the standards to be maintained, and the equipment to be used, at premises used for the manufacturing of therapeutic goods for use in humans; or

(b) procedures for quality assurance and quality control to be employed in the manufacturing of therapeutic goods for use in humans; or

(c) the qualifications and experience required of persons employed in the manufacture of therapeutic goods for use in humans; or

(d) the manufacturing practices to be employed in the manufacturing of therapeutic goods for use in humans; or

(e) other matters relevant to the quality, safety and efficacy of therapeutic goods for use in humans that are manufactured in Australia;

and may include codes of good manufacturing practice.

(4) Manufacturing principles are legislative instruments.

(5) Despite subsection 14(2) of the *Legislation Act 2003*, the manufacturing principles may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

37 Application for licence

(1) An application for a licence must:

(a) be made in accordance with a form approved by the Secretary; and

(b) identify the therapeutic goods or classes of therapeutic goods that the applicant proposes to manufacture; and

(c) in accordance with subsections (1A) and (1B), identify one or more manufacturing sites that will be used in the manufacture of those goods; and

(d) identify the steps in the manufacture of those goods that the applicant proposes to carry out under the licence; and

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(da) if the applicant proposes to carry out steps in the manufacture of blood or blood components under the licence—contain information relating to those steps set out in regulations made for the purposes of this paragraph; and

(e) state the names, qualifications and experience of the persons who are to have control of the production of the goods and of the quality control measures that are to be employed; and

(f) be delivered to an office of the Department specified in the form; and

(g) be accompanied by the prescribed application fee; and

(h) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—be accompanied by a statement from the applicant certifying that the manufacture in Australia of the therapeutic goods or classes of therapeutic goods the subject of the application will not contravene those prohibitions; and

(i) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—be accompanied by a statement from the applicant certifying that the manufacture in Australia of the therapeutic goods or classes of therapeutic goods the subject of the application will not contravene those conditions.

Manufacturing sites

(1A) Subject to subsection (1B), an application under subsection (1) must relate to one manufacturing site only. This does not prevent other applications from relating to other manufacturing sites.

(1B) If an applicant is of the view that, having regard to the guidelines under section 38A, a licence could be granted covering 2 or more manufacturing sites, the applicant may:

(a) identify those sites in the application; and

(b) state the applicant’s reasons for the applicant’s view.

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Further information

(2) The Secretary may, by notice in writing given to an applicant for a licence, require the applicant:

(a) to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or

(b) to allow an authorised person, at any reasonable time specified in the notice, to inspect each manufacturing site identified in the application and the equipment, processes and facilities that will be used in the manufacture of the goods, or other goods at that site.

Applications or information may be given electronically

(3) An approval of a form mentioned in paragraph (1)(a), or a notice mentioned in subsection (2), may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

38 Grant of licence

(1) Where:

(a) a person has made an application to carry out steps in the manufacture of therapeutic goods at one or more manufacturing sites; and

(b) the prescribed application fee has been paid; and

(c) any applicable prescribed inspection fees have been paid; and

(d) the applicant has complied with any requirements made by the Secretary under subsection 37(2) in relation to the application;

the Secretary must grant the applicant a licence covering one or more manufacturing sites specified in the licence unless the Secretary is satisfied that:

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(e) the applicant will be unable to comply with the manufacturing principles; or

(f) one or more of the manufacturing sites identified in the application are not satisfactory for the manufacture of the goods; or

(fa) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the manufacture in Australia of the goods would contravene one or more of those prohibitions; or

(fb) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the manufacture in Australia of the goods would contravene one or more of those conditions; or

(g) at least one of the following persons:

(i) the applicant;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the applicant's affairs;

(iii) if the applicant is a body corporate—a major interest holder of the body corporate;

has, within the 10 years immediately before the application:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a manufacturing licence; or

(ix) had a manufacturing licence suspended or revoked; or

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(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 year period, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

(h) any other circumstances prescribed by the regulations for the purposes of this paragraph exist.

Interpretation

(1A) A reference in paragraph (1)(g) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1AA) Paragraph (1)(g) does not limit paragraph (1)(h).

(1B) In paragraph (1)(g):

manufacturing licence means:

(a) a licence granted under this Part; or

(b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

Special circumstances justifying grant of licence

(2) Notwithstanding paragraph (1)(g), the Secretary may grant a licence to an applicant who, apart from this subsection, could not be granted a licence because of that paragraph if, in the opinion of the Secretary, special circumstances make it appropriate to do so.

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Guidelines

(2A) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

What the licence authorises

(2B) For each manufacturing site covered by a licence, the Secretary must authorise, in the licence, the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Note 2: Sections 40A and 40B deal with variation of authorisations.

Notice of decision

(3) Where the Secretary grants or refuses to grant a licence to an applicant, the Secretary must:

(a) give the applicant written notice of the decision; and

(b) in the case of a refusal—include in the notice the reasons for the refusal.

Publication

(4) Where the Secretary grants a licence, the Secretary must cause particulars of the decision to be published in the *Gazette* or on the Department's website as soon as is practicable after the decision is made.

38A Guidelines for multi-site licences

The Secretary must, by legislative instrument, make guidelines setting out the circumstances in which a licence may cover 2 or more manufacturing sites.

38B Splitting multi-site licences

(1) This section applies if a licence (the ***old licence***):

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(a) either:

(i) was in force under this Part immediately before the commencement of this section; or

(ii) was suspended under this Part immediately before that commencement; and

(b) related to premises that comprise 2 or more sites (the ***old sites***).

(2) As soon as practicable after the commencement of this section, the Secretary must:

(a) by writing, revoke the old licence; and

(b) on the day that the Secretary revokes the old licence, grant new licences (each of which is a ***new licence***) to the holder of the old licence which, when considered together, cover the old sites.

The Secretary must give the holder written notice of the revocation and grant.

Note: Subsections (5) and (6) deal with when each new licence commences and when the old licence ends.

Guidelines

(3) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

Application of this Part

(4) Subject to this section, subsections 38(2B) and (4) and sections 39 to 41A apply to a new licence in the same way as they apply to a licence granted under section 38.

Note: This means, for example, that:

(a) the Secretary must give a manufacturing site authorisation under subsection 38(2B) in relation to each manufacturing site covered by a new licence; and

(b) the Secretary may impose conditions on a new licence under subsection 40(1) and the statutory conditions under subsection 40(4) will apply to a new licence; and

(c) the Secretary may revoke or suspend a new licence under section 41.

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Commencement of new licence

(5) The day specified under subsection 39(1) for the commencement of each new licence granted to the holder of the old licence must be the day (the ***transition day***) after the day each new licence is granted.

Note: Subsection (7) deals with suspending a new licence from the transition day.

When revocation of old licence takes effect

(6) The revocation of the holder's old licence takes effect immediately before the start of the transition day.

Suspension of new licence

(7) If:

(a) subparagraph (1)(a)(ii) applies in relation to an old licence; and

(b) the period of suspension of the old licence is due to end at the end of a day (the ***relevant day***) after the transition day;

the Secretary may, on the day that the Secretary grants a new licence to the holder of the old licence and by notice in writing given to the holder, suspend the new licence for a period starting on the transition day and ending at the end of the relevant day.

(8) Subsection 41(2) does not apply in relation to a suspension under subsection (7) of this section. However, subsections 41(4) to (6) do apply in relation to the suspension.

(9) To avoid doubt, subsection (7) does not prevent subsection 41(1) from applying in relation to a new licence.

Licence charges

(10) Subsection 4(2) of the *Therapeutic Goods (Charges) Act 1989* does not apply in relation to a new licence for the financial year in which the new licence is granted.

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No review of revocation of old licence

(11) The revocation of the old licence is taken not to be an initial decision for the purposes of section 60.

39 Term of licence

(1) A licence commences on the day specified in the licence and remains in force until it is revoked or suspended.

(2) If:

(a) the licence covers therapeutic goods that are exempt under section 18A; and

(b) those goods cease to be exempt under that section before the licence is revoked;

the licence ceases to be in force in relation to those goods when those goods cease to be exempt under that section.

Note: An exemption under section 18A may cease to have effect only in relation to some of the goods covered by the exemption, see subsection 18A(5).

(3) If:

(a) the licence covers a biological that is exempt under section 32CB; and

(b) the biological ceases to be exempt under that section before the licence is revoked;

the licence ceases to be in force in relation to the biological when the biological ceases to be exempt under that section.

Note: An exemption under section 32CB may cease to have effect only in relation to some of the biologicals covered by the exemption: see subsections 32CB(5) and 32CD(1).

40 Conditions of licences

(1) A licence may be granted subject to such conditions relating to the manufacture of the goods as the Secretary thinks appropriate.

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(2) The Secretary may, by notice in writing given to the holder of a licence, impose new conditions on the licence or vary or remove existing conditions.

(3) The imposition, variation or removal of a condition under subsection (2) takes effect:

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(b) in any other case—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day.

(3A) For the purposes of paragraph (3)(b), the earlier day must not be earlier than the day the notice is given to the person.

(4) In addition to any conditions imposed under subsection (1) or (2), each licence is, except as otherwise specified in the licence, subject to the conditions that the holder of the licence will:

(a) ensure that:

(i) the goods conform to any standard applicable to the goods; and

(ii) the holder of the licence observes the manufacturing principles in carrying out any steps in the manufacture of the goods under the licence;

unless:

(iii) the goods are a biological and are for supply after the circumstances prescribed by the regulations for the purposes of paragraphs 14(9A)(b) and 14A(2A)(b) have occurred; or

(iv) the goods are a biological and are for export after the circumstances prescribed by the regulations for the purposes of paragraphs 14(13A)(b) and 14A(3A)(b) have occurred; and

(aa) if:

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(i) the holder of the licence carries out, or proposes to carry out, steps in the manufacture of blood or blood components under the licence; and

(ii) regulations made for the purposes of this paragraph set out particular information relating to those steps;

comply with a request by the Secretary to provide such information, in accordance with those regulations; and

(ab) as soon as the holder of the licence becomes aware of information of a kind mentioned in subsection (5), give the information to the Secretary in writing; and

(ac) give the Secretary the information specified in a notice under subsection (6) within the period, and in the manner, specified in the notice; and

(b) allow an authorised person:

(i) to enter, at any reasonable time, each manufacturing site covered by the licence; and

(ii) while at such a site, to inspect the site, any therapeutic goods at the site and the processes relating to the manufacture of therapeutic goods at the site and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods at the site or any thing at the site that relates to any therapeutic goods; and

(iii) while at such a site, to make any still or moving image or any recording of that site or those goods or processes; and

(c) where an authorised person enters a site as mentioned in subparagraph (b)(i), require the holder or his or her employees at that site to answer questions relating to procedures carried out at that site; and

(d) if requested to do so by an authorised person:

(i) produce to the person such documents relating to the manufacture of therapeutic goods manufactured at that site as the person requires and allow the person to copy the documents; or

(ii) produce to the person for examination any batch samples kept by the holder; and

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(e) comply with such other conditions (if any) as are specified in the regulations for the purposes of this section.

(5) The information with which paragraph (4)(ab) is concerned is information of the following kinds:

(a) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;

(b) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as was suggested by:

(i) the application for registration or listing of the goods; or

(ii) information already furnished by the holder of the licence under this Act; or

(iii) if the holder of the licence is not the sponsor of the goods—information already furnished by the sponsor of the goods under this Act;

(c) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

(6) The Secretary may, by notice in writing given to the holder of a licence, require the holder to give the Secretary, within the specified period and in the specified manner, specified information to be used by the Secretary in deciding whether to revoke or suspend the licence under section 41 in the circumstances referred to in paragraph 41(1)(a).

(7) The period specified in a notice given under subsection (6) must be at least 14 days after the notice is given.

40A Variation of manufacturing site authorisations—Secretary's own initiative

(1) The Secretary may, on his or her own initiative and by notice in writing given to the holder of a licence, vary a manufacturing site authorisation in relation to the licence.

(2) A variation under subsection (1) takes effect:

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(a) if the notice states that the variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the holder; or

(b) in any other case—on the day specified in the notice (which must not be earlier than 28 days after the notice is given to the holder).

40B Variation of licences—application by licence holder

Addition of manufacturing sites

(1) If the holder of a licence is of the view that, having regard to the guidelines under section 38A, the licence could cover one or more additional manufacturing sites, the holder may apply to the Secretary for a variation of the licence so that it covers one or more additional manufacturing sites specified in the application.

(2) An application under subsection (1) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) identify the therapeutic goods or classes of therapeutic goods that the holder proposes to manufacture at each additional manufacturing site specified in the application; and

(c) identify the steps in the manufacture of those goods that the holder proposes to carry out under the licence; and

(d) if the holder proposes to carry out steps in the manufacture of blood or blood components under the licence—contain information relating to those steps set out in regulations made for the purposes of paragraph 37(1)(da); and

(e) state the names, qualifications and experience of the persons who are to have control of the manufacture of the goods and of the quality control measures that are to be employed; and

(f) be delivered to an office of the Department specified in the form; and

(g) be accompanied by the prescribed application fee.

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(3) If an application is made under subsection (1) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence covers each additional manufacturing site specified in the notice.

(4) For each manufacturing site specified under subsection (3), the Secretary must, in the notice under that subsection, vary the licence to authorise the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Note 2: Section 40A and subsections (6) to (9) of this section deal with variation of authorisations.

(5) A variation under subsection (3) or (4) takes effect on the day on which the notice is given to the holder.

Variation of manufacturing site authorisations

(6) The holder of a licence may apply to the Secretary for a variation of a manufacturing site authorisation in relation to the licence.

(7) An application under subsection (6) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) set out the variation sought; and

(c) be delivered to an office of the Department specified in the form; and

(d) be accompanied by the prescribed application fee.

(8) If an application is made under subsection (6) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the manufacturing site authorisation.

(9) A variation under subsection (8) takes effect on the day on which the notice is given to the holder.

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Removal of manufacturing sites

(9A) The holder of a licence may apply to the Secretary for a variation of the licence so that it ceases to cover one or more manufacturing sites specified in the application.

(9B) An application under subsection (9A) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) be delivered to an office of the Department specified in the form; and

(c) be accompanied by the prescribed application fee.

(9C) If an application is made under subsection (9A), the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence does not cover each manufacturing site specified in the notice.

(9D) A variation under subsection (9C) takes effect on the day specified in the notice.

Further information

(10) The Secretary may, by notice in writing given to the holder of a licence who has made an application under subsection (1), (6) or (9A), require the holder:

(a) to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or

(b) for an application under subsection (1) or (6)—to allow an authorised person, at any reasonable time specified in the notice, to inspect each manufacturing site identified in the application and the equipment, processes and facilities that will be used in the manufacture of therapeutic goods at that site.

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Applications or information may be given electronically

(11) An approval of a form mentioned in paragraph (2)(a), (7)(a) or (9B)(a), or a notice mentioned in subsection (10), may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

41 Revocation and suspension of licences

(1) Subject to subsection (2), the Secretary may, by notice in writing given to the holder of a licence, revoke the licence, or suspend the licence for a period specified in the notice, if:

(a) at least one of the following persons:

(i) the holder;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs;

(iii) if the holder is a body corporate—a major interest holder of the body corporate;

has:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a manufacturing licence; or

(ix) had a manufacturing licence suspended or revoked; or

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(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

(d) the holder requests in writing that the licence be revoked or suspended, as the case may be; or

(e) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or

(ea) the holder contravenes a manufacturing site authorisation in relation to the licence; or

(f) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days after they become payable; or

(g) the goods are exempt under section 18A and the holder has breached a condition of the exemption in relation to those goods; or

(ga) the licence covers a biological that is exempt under section 32CB and the holder has breached a condition of the exemption in relation to the biological; or

(gb) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the Secretary is satisfied that the manufacture in Australia of the goods to which the licence relates would contravene one or more of those prohibitions; or

(gc) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the Secretary is satisfied that the manufacture in Australia of the goods to which the licence relates would contravene one or more of those conditions; or

(h) any other circumstances prescribed by the regulations for the purposes of this paragraph exist.

(1A) A reference in paragraph (1)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

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(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1B) Paragraph (1)(a) does not limit paragraph (1)(h).

(1C) In paragraph (1)(a):

manufacturing licence means:

(a) a licence granted under this Part; or

(b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

(2) Where the Secretary proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Secretary must, unless the Secretary considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury:

(a) by notice in writing given to the holder, inform the holder of the action that the Secretary proposes to take and of the reasons for that proposed action; and

(b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable prescribed inspection fee—give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Secretary in relation to the proposed action.

(3) Where the holder makes submissions in accordance with paragraph (2)(b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.

(4) A licence may be revoked notwithstanding that the licence is suspended.

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(5) Where a licence is suspended, the Secretary may, by notice in writing given to the holder of the licence, revoke the suspension.

(6) Where the Secretary revokes or suspends a licence, the Secretary must cause particulars of the decision to be published in the *Gazette* or on the Department's website as soon as is practicable after the decision is made.

41AAAA Withdrawal of revocation of licence upon request

(1) If:

(a) the Secretary revokes a licence because of the request of a person made under paragraph 41(1)(d); and

(b) before the end of the period of 90 days beginning on the day the licence was revoked, the person requests, in writing, the Secretary to withdraw the revocation; and

(c) the request is accompanied by the prescribed application fee (if any);

the Secretary may, by notice in writing given to the person, withdraw the revocation.

(2) If the revocation is withdrawn, the revocation is taken never to have occurred.

41AA Spent convictions scheme

Nothing in section 40 or 41 affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

41AB Secretary may require information or documents

(1) If:

(a) a person is the holder of a licence; and

(b) the person has carried out, or is carrying out, one or more steps in the manufacture of therapeutic goods;

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the Secretary may, by written notice given to the person, require the person to:

(c) give the Secretary information, or produce to the Secretary documents, relating to one or more of the following:

(i) the therapeutic goods;

(ii) if the therapeutic goods consist of a mixture of ingredients—those ingredients;

(iii) if the therapeutic goods consist of a mixture of ingredients—the suppliers of those ingredients;

(iv) if the therapeutic goods consist of a combination of component parts—those component parts;

(v) if the therapeutic goods consist of a combination of component parts—the suppliers of those component parts;

(vi) the containers or packages used, or proposed to be used, to contain the therapeutic goods;

(vii) the batch numbers of the therapeutic goods;

(viii) the expiry dates of the therapeutic goods;

(ix) the distribution of the therapeutic goods;

(x) the conformity of the therapeutic goods to a standard applicable to the goods;

(xi) the step or steps that the person has carried out, or is carrying out, in the manufacture of the therapeutic goods;

(xii) the premises used to carry out one or more steps in the manufacture of the therapeutic goods;

(xiii) the observance of the manufacturing principles;

(xiv) the names, qualifications and experience of individuals who have control of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

(xv) the measures for quality assurance and quality control employed in the taking of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

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(xvi) compliance with the conditions of the licence;

(xvii) whether there are grounds for revoking or suspending the licence;

(xviii) any other matter that is prescribed by the regulations and that relates to the manufacture of the therapeutic goods; and

(d) do so:

(i) within such reasonable time as is specified in the notice; and

(ii) in such form as is specified in the notice.

(2) The time specified in the notice must not be shorter than 14 days after the notice is given.

(3) The rule in subsection (2) does not apply if the Secretary is satisfied that, because of circumstances of urgency, the time specified in the notice should be shorter than 14 days after the notice is given.

(4) An approval of a form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

41AC Criminal offence for contravening a requirement in a notice under section 41AB

A person commits an offence if:

(a) the person has been given a notice under section 41AB; and

(b) the person omits to do an act; and

(c) the omission contravenes a requirement in the notice.

Penalty: 400 penalty units.

41AD False or misleading information—offence

(1) A person commits an offence if:

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(a) the person is given a notice under section 41AB; and

(b) the person gives information to the Secretary in compliance, or purported compliance, with the notice; and

(c) the person does so knowing that the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(2) Subsection (1) does not apply as a result of subparagraph (1)(c)(i) if the information is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2).

(3) Subsection (1) does not apply as a result of subparagraph (1)(c)(ii) if the information did not omit any matter or thing without which the information is misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3).

41AE False or misleading documents—offence

(1) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the person does so knowing that the document is false or misleading; and

(c) the document is produced in compliance, or purported compliance, with a notice given under section 41AB.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(2) Subsection (1) does not apply if the document is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2).

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(3) Subsection (1) does not apply to a person who produces a document if the document is accompanied by a written statement signed by the person or, in the case of a body corporate, by a competent officer of the body corporate:

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and

(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3).

41AF False or misleading information or documents—civil penalty

(1) A person contravenes this section if:

(a) the person is given a notice under section 41AB; and

(b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

(2) Subsection (1) does not apply to a person who produces a document if the document is accompanied by a written statement signed by the person or, in the case of a body corporate, by a competent officer of the body corporate:

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and

(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

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41AG Self-incrimination

(1) A person is not excused from giving information or a producing a document under a section 41AB notice on the ground that the giving of the information or the production of the document would tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; or

(b) the giving of the information or the production of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, section 41AD or 41AE; or

(e) proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision.

41AAA Transfer of licences

(1) The regulations may make provision for and in relation to the transfer of licences.

(2) Regulations made for the purposes of subsection (1) may make provision for and in relation to:

(a) the making of an application for the transfer of a licence; and

(b) the payment of a fee in respect of an application; and

(c) the assessment of an application; and

(d) the conditions of a licence upon the transfer of the licence; and

(e) the review of decisions made under the regulations.

(3) Subsection (2) does not limit subsection (1).

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41A Publication of list of manufacturers etc.

The Secretary may, from time to time and in such manner as the Secretary determines, publish a list of the persons who are licensed under this Part, the classes of goods to which the licences relate, the steps of manufacture that the licences authorise and the addresses of the manufacturing sites to which the licences relate.

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